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**PROVIDING INCENTIVES TO INDUSTRY
TO DEVELOP NEW CONTRACEPTIVES**

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I. Introduction

In ancient China, women were advised to swallow twenty— four live tadpoles in the spring to prevent conception for the following five years.’ In the Talmud, written around 200 A.D., the Hebrews described the use of spongy substances used by women trying to prevent sperm from entering the womb.² Centuries later in the mid—1700s, Italian adventurer Giovanni Casanova advocated women’s use of half a lemon from which the juice had been extracted, as a cervical cap to be worn during intercourse to hinder conception.³

These historical examples demonstrate that methods of contraception have been discussed for ages. Yet, despite its long history, contraceptive science has hardly advanced beyond these primitive practices. The synthesis of the first oral contraceptive (the Pill) in 1951, and its subsequent distribution in 1960, is clearly the most remarkable breakthrough in recent times. Unfortunately, this achievement is notable also for its singularity. Only limited progress has been made in contraceptive development in the thirty-five years since the Pill became available. The slow pace of development has been particularly problematic in the United States, leaving Americans with few contraceptive alternatives.

¹ *Backgrounder: Oral Contraceptives* (Ortho Pharmaceutical Corp., Raritan, N.J.), Oct. 14, 1992, at 1.

² Robin Berman, *Whatever Happened to the Contraceptive Revolution*, WASH. POST, Dec. 14, 1994 (Health), at 12, 15.

³ *Id.*

This paper will discuss why this lack of contraceptive alternatives poses such a tremendous problem, and will describe the birth control options currently available. Additionally, the paper will describe the four main reasons for the lack of progress in contraceptive development: a deluge of product liability suits; negative political pressures; the large expense of testing products intended for a healthy population; and insufficient research and funding. Finally, the paper will offer some proposals for addressing each of these problems.

II. The Need for More Contraceptives

In February 1990, the National Research Council's Committee on Contraceptive Development (NRCCCD) released a report based on its two-year study of the development and approval process for contraceptives in the United States. The committee concluded that current contraceptive choices were inadequate. Furthermore, they found that because decisions about contraception affect the vast majority of people in the U.S., developing additional methods that are safe, effective and acceptable within the cultural, social, religious, and ethical frameworks ... of society would have a significant positive effect on human well-being.⁴

The societal ramifications of having only a limited number of contraceptive options is clearly demonstrated

⁴Luigi Mastrojanni, Jr. et al., *Special Report: Development of Contraceptives – Obstacles and Opportunities*, 322 NEW ENG. J. MED. 482 (1990).

through recent public health statistics. According to data compiled by The Washington Post, fifty-seven percent (3.6 million) of all pregnancies in the United States each year are unplanned.⁵ Moreover, American teens have higher pregnancy rates than their counterparts in other Western countries despite equivalent rates of sexual activity.⁶ The problem of unplanned pregnancy is not limited to teenagers—indeed, eighty percent of unplanned pregnancies in this country are to women twenty years or older.⁷ Almost half of these unplanned pregnancies end in abortion, the rest result in births. As a result, about thirty percent of all pregnancies in the U.S. end in abortion, a rate higher than any other industrialized nation.⁸ Moreover, because of the dearth of options available, the draconian choice of irreversible female sterilization, i.e., the clamping or cauterization of the Fallopian tubes, is the second most popular form of birth control for American women, after oral contraceptives. Twelve percent of married women under thirty years of age have had this operation.⁹

⁵Berman, *supra* note 2, at 12. Although the enormous social costs of these unplanned pregnancies in terms of health care, missed educational and work opportunities for the parents and children, and the burdens on the American welfare system are certainly troubling, an analysis of these issues is beyond the scope of this paper.

⁶Kim Painter, *The Imperfect State of Birth Control in the USA*, USA TonAz, Mar. 16, 1992, at 4D.

⁷Berman, *supra* note 2, at 12. Still, American teenage pregnancy rates are high: 21% of teens ages 15—19 who have had sexual intercourse became pregnant last year, i.e., 12% of all women in this age group. *Id.* ⁸*Id.* The abortion rate in Great Britain is 16% of all pregnancies; in Canada, the rate is 17%. *Id.*

⁹*Id.*

In light of these statistics, the demand for contraceptives seems indisputable. Nevertheless, pharmaceutical companies are not acting to meet that demand. Only thirty years ago, thirteen American companies were researching contraceptives, including some large pharmaceutical companies like Upjohn, Syntex, and G.D. Searle.¹⁰ In addition, as recently as 1978, *Advertising Age* was contemplating Proctor & Gamble's entry into the huge business [of contraception] ... that appears ripe for change. However, today only Ortho Pharmaceutical Corp., a division of Johnson & Johnson, does significant in-house research in this field. Although Wyeth—Ayerst, another large firm, distributes Norplant, the research on Norplant was performed by the Population Council, a non-profit research foundation founded by John D. Rockefeller, and the firm will share its profits with the Council. According to the Council, its own modest size slowed the pace of the project, and development of Norplant took four times as long as it would have at a large pharmaceutical company.¹² Indeed, Dr.

C. Wayne Bardin of the Population Council, asserts that developing contraceptives this way, is good only if you are opposed to contraception It takes us a very long time to bring a contraceptive to market.¹³

¹⁰*Id.* at 13.

Larry Edwards, *P & G's Contraceptive Work Could Shake Up Market*, *ADVERTISING AGE*, Oct. 30, 1978, at 6.

¹²Herman, *supra* note 2, at 14.

¹³Philip J. Hilts, *Birth Control Backlash*, N.Y. TIMES, Dec. 16, 1990 § 6 (Magazine), at 41, 55.

Several reasons have been offered for the lack of interest in contraceptive development. According to Roderick

L. Mackenzie, former president of Ortho Pharmaceutical Corp. and current chairman of GynoPharma, the small company that markets a copper intra—uterine device (IUD), large companies abandoned the birth control business because of the enormous challenges they faced. Noting that the industry has not encountered a very encouraging atmosphere, Mackenzie suggests that the increasing costs of litigation combined with criticisms from Congress, the Food and Drug Administration (FDA), and women's groups, and the absence of potentially lucrative research led pharmaceutical firms to leave the contraception market.⁴ Generally, difficulties encountered in four areas – product liability, politics, testing, and funding – have contributed to the current state of contraceptive development. Each of these problem areas will be discussed in detail below.

III. Contraceptives Currently Available

To better understand the pressing need for additional methods of birth control, an examination of the methods currently available is necessary, including a discussion of how the methods work, their safety, efficacy and popularity.⁵ The most effective methods of reversible contraception on the

⁴*Id.*

⁵Because women bear most of the burden of conception, they are the primary users of birth control. Consequently, the reader should assume that the methods described are intended for use by women, unless otherwise noted.

market today involve means of delivering forms of two female reproductive hormones — estrogen and progesterone — to help regulate ovulation, the condition of the uterine lining, and other parts of the menstrual cycle.¹⁶ The most popular contraceptive since 1969 is the birth control pill. Today there are approximately seventeen million Pill users in the United States, representing one-quarter of all women of child-bearing age.¹⁷ More than one-third of these women are over thirty years old.¹⁸

Two types of birth control pills are sold in the United States — combination pills which include both estrogen and progestin (a synthetic form of progesterone), and mini-pills containing just progestin.¹⁹ Combination pills prevent pregnancy by preventing ovulation. Currently, there are nineteen different combination pills on the market and their failure rate is about one to two percent.²⁰ The mini—pills prevent pregnancy by reducing cervical mucus and causing it to thicken, thereby hindering the sperm's ability to reach the ovum. Also, these progestins keep the endometrium from thickening, preventing fertilized eggs from implanting in the

¹⁶Merle S. Goldberg, *Choosing A Contraceptive*, FDA CONSUI4ER, Sept. 1993, at 23.

¹⁷Serman, *supra* note 2, at 14.

¹⁸*Highlights of the 1993 Annual Birth Control Study* (Ortho Pharmaceutical Corp., Raritan, N.J.), 1994. Ortho has been conducting annual birth control studies since 1969. Its 1993 study surveyed 8,000 women ages 15 to 50 years and then weighted the sample by age, marital status, and geographic distribution to reflect national demographics. *Id.*

¹⁹Goldberg, *supra* note 16. ²⁰Berman, *supra* note 2, at 14.

uterus. The mini—pill has a one to three percent failure rate.²¹

The average length of use for birth control pills is 5.5 years. Combination oral contraceptives offer significant protection against ovarian cancer, endometrial cancer, iron—deficiency anemia, pelvic inflammatory disease, fibrocystic breast disease, and ovarian cysts. Possible serious risks associated with use of the Pill include blood clots, stroke, and heart attacks, especially if the user smokes and is over thirty-five years of age. Some studies indicate increased risk of breast cancer, but the evidence remains equivocal.²² Minor side effects, which usually subside after a few months' use, include nausea, headaches, breast swelling, fluid retention, weight gain, irregular bleeding, and depression.²³

Women may also take a pill containing high doses of estrogen to cause an almost immediate shedding of the endometrium and prevent implantation of the fertilized ovum. This birth control method is usually employed as a postcoital contraceptive, and is often referred to as the morning—after pill.²⁴ It is simply a variation on the usage of hormonal birth control pills and ordinarily involves the ingestion of Ovral, i.e., 200 mg. of ethinyl estradiol, within seventy-two hours of intercourse, followed by additional hormonal pills twelve hours later.²⁵

Side effects

²¹Goldberg, *supra* note 16.

²²Ortho 1993 Study, *supra* note 18.

²³Goldberg, *supra* note 16.

²⁴*Choice of Contraceptives*, 34 MED. LETTER 111, 113 (1992).

of Ovral and other high dosage hormonal contraceptives may include breast tenderness, nausea and vomiting. Indeed, Ovral users risk vomiting the pills before they take effect. Because it is essentially a different dosage of oral contraception, the potential long-term adverse effects of this method are the same as those for other hormonal pills.²⁶

Norplant offers women the option of an implant of the same hormones available in oral contraceptives. Approved by the FDA in 1990, Norplant involves the surgical implantation of six matchstick—sized rubber capsules containing progestin just underneath the skin of the upper arm. Norplant provides contraceptive protection for five years, or until it is removed. Because the method is not user—dependent, the failure rate for Norplant is less than one percent. The potential risk factors and side effects are similar to those described for the birth control pill.²⁷

Depo Provera, an injectible form of progestin, was originally approved by the FDA in the 1960s for the treatment of endometrial and renal cancers. While it has been prescribed by physicians for contraceptive use for decades, it has only had FDA approval as a contraceptive since 1992.²⁸ Depo Provera must be injected into a muscle in the buttocks or arm by a health care professional every three months. Each injection provides contraceptive protection for fourteen

²⁶Jan Hoffman, *The Morning-After Pill, A Well-Kept Secret*, N.Y. TIMES, Jan. 10, 1993, S 6 (Magazine), at 12, 13.

²⁷Goldberg, *supra* note 16, at 24.

²⁸*Advisory Panel Recommends Approval for Depo Provera*, FDA TALK PAPER

(FDA, Rockville, Md.), June 19, 1992.

weeks, and this method has a failure rate of only one percent. The potential risks and side effects are similar to those outlined for oral contraceptives and Norplant.²⁹

Intra-uterine devices (IUDs) are small plastic flexible devices inserted into the uterus through the cervix by a health care professional. Only two IUDs are presently marketed in the United States – ParaGard T380A manufactured by GynoPharma, which is a T-shaped device partially covered by copper and effective for eight years, and Progestasert, a T—shaped device manufactured by Alza that releases progestin over a one year period. Both IUDs have a four to five percent failure rate. Scientists are not certain how the IUD prevents pregnancy. Previously, researchers had reported that the IUD worked by making the uterus inhospitable to implantation. However, more recent evidence indicates that IUDs (particularly those containing copper) alter uterine and tubal fluids inhibiting the transport of sperm through the cervical mucus and uterus.³⁰ The TUD is recommended for women in mutually monogamous relationships because of links between the incidence of pelvic inflammatory disease (PID) and IUDs, particularly in women with multiple sex partners. In addition to PID, other risks from IUDs include perforation of the uterus at time of insertion, septic abortion, or ectopic pregnancy.³¹

²⁹Goldberg, *supra* note 16, at 24.

³⁰*Id.* at 24, 25.

³¹*Id.*

Each of the methods described above is considered to be a chemical method of contraception, and each of them requires a prescription from a physician. Presently, spermicides are the only chemical method of birth control available without a prescription. Nonoxynol—9, the most commonly used spermicide in the U.S., is a chemical surfactant that destroys the cell walls of sperm and offers some protection against sexually transmitted diseases (STDs). Spermicides come in several forms, including foam, vaginal suppositories, and jelly. In addition, condoms are often lubricated with spermicide. The primary risk associated with spermicides is local irritation in both men and women and/or allergic reactions.³² The efficacy rate for contraception by spermicides used alone ranges from seventy to eighty percent.³³

In addition to the chemical means of preventing conception, there are five barrier methods: male condom, female condom, diaphragm, sponge and cervical cap. These methods work by keeping the sperm and ovum apart.³⁴ The male condom, relied upon by nineteen percent of all women, is the second most frequently used method of reversible birth control. Available without a prescription, the male condom has a failure rate of fifteen percent, mostly as a result of improper use.³⁵ Statistics indicate that the majority of women who rely on male condoms as their method of

³²Choice of Contraceptives, *supra* note 24, at 113.

³³Goldberg, *supra* note 16, at 19.

³⁴*Id.*

³⁵Goldberg, *supra* note 16, at 22.

contraception are under age thirty, and that forty-two percent of all women and two-thirds of all unmarried women use condoms, often in addition to another method, because of fears of STDs.³⁶ Indeed, according to the FDA, the male latex condom is the only form of birth control considered highly effective in helping protect against human immuno—deficiency virus (HIV) and STDs.³⁷

The female condom, currently marketed by Wisconsin Pharmacal under the name Reality was approved by the FDA in April 1993. This over-the-counter product consists of a lubricated polyurethane sheath with a flexible polyurethane ring on each end. One ring is inserted into the vagina to cover the cervix, while the other remains outside, partially covering the labia. The estimated yearly failure rate for the female condom is twenty-one to twenty-six percent. Although it is currently the only device women can use themselves to guard against STDs, the female condom does not offer full protection against disease.³⁸ Other female condoms currently being tested are Women's Choice which is similar to the Reality condom, but is made of latex, and the Bikini, a latex pouch resembling underwear, which is pushed inside the vagina by the penis.³⁹ Potential side effects of

³⁶Ortho 1993 Study, *supra* note 18.

³⁷Goldberg, *supra* note 16, at 19. Consequently, in April, 1993, the FDA announced that oral contraceptives, Norplant, Depo Provera and IUDs must carry labeling stating that these products are intended to prevent pregnancy but do not protect against BIV infection or other STDs. *Id.* ³⁸Goldberg, *supra* note 16, at 22.

³⁹Choice of Contraceptives, *supra* note 24, at 114.

male and female condoms include local irritation or allergic reactions ⁴⁰

The diaphragm, a flexible rubber disk with a rigid rim, covers the cervix during and after intercourse. Diaphragms range in size from two to four inches and women must be measured by a health care professional to ensure proper fit. The diaphragm used with spermicide has a failure rate of six to eighteen percent.⁴¹ According to the 1993 Birth Control Study by Ortho Pharmaceutical Corp., diaphragms are used by three percent of women of child-bearing age.⁴² Potential side effects of this method are bladder infections and toxic shock syndrome (TSS), a rare but potentially fatal infection.⁴³

The contraceptive sponge, approved by the FDA in 1983, is made of polyurethane foam, and shaped like a small doughnut. This over—the-counter product contains spermicide Nonoxynol-9, and like the diaphragm, is inserted into the vagina to cover the cervix during and after intercourse. The failure rate for the sponge ranges from eighteen to twenty-eight percent, and use of the product exposes women to the rare risk of TSS.⁴⁴ Although two percent of all women of child-bearing age had been using the sponge,⁴⁵ recently American Home Products, the only manufacturers of contraceptive sponges in the world, announced that they were

⁴⁰Goldlberg, *supra* note 16, at 22.

⁴¹*Id.*

⁴²Ortho 1993 Study, *supra* note 18.

⁴³Goldberg, *supra* note 16, at 22.

⁴⁴*Id.*

⁴⁵Ortho 1993 Study, *supra* note 18.

discontinuing production for economic reasons. Apparently, the company felt that profits from the sponge did not justify the expense of making their plant comply with new FDA standards ⁴⁶

The fifth barrier method currently available is the cervical cap. Approved by the FDA in 1988, the cervical cap is a dome-shaped device that fits over the cervix. The cap comes in various sizes and women must be fit by a health care professional. The cap, with a failure rate of approximately eighteen percent, may be more difficult to insert than the diaphragm, but it may be worn for forty-eight hours, and can be used without a spermicide. Side effects of the cap include unpleasant odors and/or discharge, an increased incidence of irregular Pap tests during the first six months of use, and the risk of TSS.⁴⁷

Permanent surgical sterilization is the second most popular form of birth control among American women after the Pill. If sterilization rates for American men and women are combined, then sterilization is the most popular contraceptive choice in the United States, selected by almost one-third of all Americans.⁴⁸ Male sterilization is usually accomplished through a vasectomy, i.e., the sealing of the vas deferens to prevent the travel of sperm to the penis. A vasectomy is a minor surgical procedure usually performed in

⁴⁶ *Only Manufacturer Discontinues Sponge for Contraception*, N.Y. TIMES, Jan. 11, 1995, at A17.

⁴⁷ Goldberg, *supra* note 16, at 23.

⁴⁸ Bilts, *supra* note 13.

less than thirty minutes in a physician's office.⁴⁹ Male sterilization is considered safer than its female counterpart, tubal ligation. Tubal ligation requires an operation under general anesthesia where a surgeon seals the Fallopian tubes through clips, a plastic ring or an electric current. Major complications are rare, occurring in only 1.7 percent of all cases.⁵⁰ While the failure rate for sterilization is less than one percent, the process is currently considered irreversible because physicians have had limited success in reopening the vas deferens or Fallopian tubes.

The natural family planning or rhythm method of birth control involves periodic abstinence during a woman's ten-day fertile period each month. The efficacy of this method depends on the ability to identify correctly this period of time. Two common methods of detection are the basal body temperature method and the cervical mucus (Billings) method. The body temperature method requires a woman to monitor regularly her body so that she may detect the drop in temperature during ovulation. Women using the Billings method must recognize the changes in cervical mucus that indicate that ovulation is occurring or has occurred.⁵² Periodic abstinence has none of the side effects of artificial methods of contraception. Nevertheless, this

⁴⁹Goldberg, *supra* note 16, at 25.

⁵⁰*Id.*

⁵¹*Id.*

⁵²*Id.*

method has at least one major drawback. Although new electronic measurement devices are now available to help make more accurate determinations, the rhythm method fails up to forty—seven percent of the time.⁵³

In addition to the methods currently available in the U.S., there are several products that are either under development or have been targeted for research by fertility specialists. The methods being developed for women include both improvements on existing products, such as new hormonal methods (including RU—486), medicated IUDs and short-term hormonal implants, as well as more novel items like vaginal rings, anti—viral spermicides, and an anti—fertility vaccine. An anti—fertility vaccine is also being considered for men. Other male products presently in experimental stages are sperm suppressants containing testosterone and/or cottonseed oil, and silicone sperm duct plugs.⁵⁴

IV. Some Problems Evaluating Existing Methods of Contraception

An examination of the birth control methods currently available helps demonstrate their limitations. Most notably, some methods appear to have unacceptable failure rates. Yet, while it is no doubt true that no mode of contraception is fail—safe, taking the numbers at face value may be misleading because efficacy rates for contraception are based on both

⁵³ *Id.*

⁵⁴ Herman, *supra* note 2, at 14.

proper and improper use. For example, the failure rate for perfect use of oral contraceptives is less than one percent. However, a sample of several thousand women who were taking the Pill for a year may reveal a six percent rate of pregnancy. This disparity reflects the reality that many Pill users forget to take one every day. Indeed, every contraceptive has two sets of statistics — the failure rate for perfect use and the rate for typical use.⁵⁵

Although the perfect and typical use rates are the same for methods like Depo Provera and Norplant where hormones are automatically released, the gap in the statistics may be quite wide for methods requiring more user participation and responsibility. For example, while spermicides are one of the most effective options available, women tend to use these products incorrectly, so that almost one-third of the women who rely on them become pregnant within a year.⁵⁶ Similarly, because of misuse, about one-fifth of women depending upon a diaphragm or condoms will become pregnant in the first year.⁵⁷

Because efficacy statistics reflect disparities in proper use, women may have difficulty comparing accurately one method to another. A method with a high rate of efficacy for perfect use may be so often used improperly, that its failure rate is high. Moreover, contraceptive failure rates vary by age, marital status, income, and lifestyle factors

⁵⁵Malcolm Gladwell, *Inside the Numbers On Birth Control*, WASH. POST, Dec.

28, 1992, at A3.

⁵⁶*Id*

⁵⁷Herman, *supra* note 2, at 13.

such as smoking and frequency of intercourse. While the overall first year pregnancy rate for all women using birth control is 13.8 percent, the rates vary by age, with older women having the fewest instances of contraceptive failure. Researchers attribute these statistics to the fact that skill and diligence in using birth control increases with age. In addition, for older women, intercourse is usually more predictable or planned.⁵⁸ Because of these variables, and the disparities between populations who tested the products, comparisons among products can only be estimates.⁵⁹

In addition to product failures and misuse, consumers' attitudes also affect conception rates. A 1986 study by the Alan Guttmacher Institute (AGI), a New York-based, non-profit family-planning policy organization, surveyed 760 women from low-income groups and found that many of these women were disinclined to use any method of birth control. These women had only limited knowledge about the Pill and IUD and feared the health risks of these methods.⁶⁰ Moreover, the study participants disliked barrier methods like the diaphragm and condom because they felt that the products' lower efficacy rates did not justify the discomfort the women would feel

⁵⁸Gladwell, *supra* note 55. Failure rates also vary by marital status. According to a study by the Alan Guttmacher Institute, the unplanned pregnancy rates by marital status are — married: 14.8%; previously married: 25.7%; never married: 15.9%. See Painter, *supra* note 6. ⁵⁹Gladwell, *supra* note 55.

⁶⁰Bilts, *supra* note 13, at 55. Similarly, a Gallup poll commissioned by a manufacturer of oral contraceptives found that women had several misconceptions about the risks and potential benefits of Pill use. See, *Misinformation About Birth Control Pills is Widespread, Despite High Prevalence of Use*, TIME TO TALK (Organon, Inc., New York, N.Y.), Apr. 29, 1993.

discussing birth control with their partners.⁶¹ This shyness about discussing birth control has been described as a distinctly American phenomenon not experienced by women in other Western nations.⁶² Furthermore, this difference in attitude may account for the higher rates of unintended pregnancy in the United States, particularly among teenagers, as compared to other industrialized countries.⁶³

Another part of the efficacy debate focuses on whether lower contraceptive failure rates would result from more over-the-counter alternatives, or whether advice or intervention from a health care professional regarding proper use of a contraceptive increases its efficacy. On more than one occasion, the FDA has considered the sale of over-the-counter oral contraceptives. Proponents of this proposal note that oral contraceptives are actually safer than some drugs, such as aspirin, which are easily accessible to consumers.⁶⁵ Others suggest that requiring a prescription for the Pill brings women into the doctor's office, affording physicians an opportunity to determine if the patients are appropriate candidates for the Pill, and to educate them on proper Pill use. Moreover, requiring a prescription for the most effective form of birth control available provides an

⁶¹Bilts, *supra* note 13, at 55.

⁶²*Id*

⁶³*Id*

⁶⁴Painter, *supra* note 6.

⁶⁵*Id*

incentive for women to undergo essential gynecological examinations •66

Finally, in addition to efficacy, attitudes and accessibility, health factors also determine the adequacy of existing contraceptive options for certain groups of women. For example, breast—feeding women are advised against using hormonal methods of birth control because of the possible effects of the hormones on their babies. Hypertensive or diabetic women and women who are over age thirty—five and smoke are also advised not to use hormonal methods because of increased health risks.⁶⁷ In addition to these medical safety factors, lifestyle also determines the suitability of certain methods. For example, women who engage in intercourse only sporadically, e.g., teenagers, often see the Pill or IUD as an inappropriately long-term option. Women with more than one partner also have important lifestyle considerations, and need methods which protect against both pregnancy and STDs.⁶⁸

V. Problems Limiting New Development

A. Product Liability

Experts agree that one of the key factors limiting new development of contraceptives is the pharmaceutical companies' fear of litigation. Product liability has

⁶⁶ *Id*

⁶⁷ *Serman*, *supra* note 2, at 12—13.

⁶⁸ *Id*

brought contraceptive research [in the United States] to a screeching halt, according to Richard Lincoln of AGI.⁶⁹

Reasons offered for the upsurge in product liability suits vary, with each side of the debate blaming the other. The large pharmaceutical companies see themselves as victims of greedy plaintiffs' attorneys. These industry representatives believe that they should be immune from suit once their product passes the FDA regulatory process. Many have responded to the threat of lawsuits by eliminating their contraceptive research departments and/or marketing their contraceptives overseas. Small upstart research companies have also felt the impact of these lawsuits. While they are not often targeted by plaintiffs' attorneys, they claim that the threat of litigation impairs their ability to obtain liability insurance, and consequently, their ability to market their products.⁷⁰

Plaintiffs' lawyers and consumer groups clearly have a different view. They blame the lawsuits on the pharmaceutical industry, claiming that the companies fail to test contraceptive products properly, provide unclear product labeling, and target inappropriate products to certain populations. These parties allege that the companies care little about women's health and that litigation is the only means of pressuring manufacturers to make safer products. Moreover, they believe that allowing companies to defend

⁶⁹Michele Galen, *Birth Control Options Limited by Litigation*, NAIRL L.J., Oct. 20, 1986, at 1, 26.

⁷⁰*Id.*

themselves based on compliance with FDA standards would enable the firms to mask flawed pre-market tests, particularly in light of the close relationship between the FDA and industry.⁷¹

The impasse between companies and consumers reflects in part the long history of litigation involving contraceptives since the distribution of the Pill in 1960. Since the late 1960s, oral contraceptive users have sued manufacturers sporadically, mainly for failing to warn of the risks of blood clots and stroke.⁷² However, the litigation problem mushroomed with the development and distribution of the Dalkon Shield IUD by A.H. Robins in 1971.~~

When the Dalkon Shield was first marketed, the FDA did not require pre-screening of such medical devices for safety and efficacy. An apparent internal design flaw in the Dalkon Shield caused pelvic and uterine infections, ectopic pregnancies, and infertility in thousands of women.⁷⁴ Under

⁷¹ *Id.*

⁷² Plaintiffs have been successful in many of these failure to warn claims over the years. *See, e.g., Leibowitz v. Ortho Pharmaceutical CorD.*, 307 A.2d 449 (Pa. 1972); *Lindsay v. Ortho Pharmaceutical Core.*, 481 F. Supp. 314 (E.D.N.Y. 1979); *Ortho Pharmaceutical CorD. v. Chatman*, 388 N.E.2d 541 (Ind. 1979); *Brochu v. Ortho Pharmaceutical CorD.*, 642 F.2d 652 (1st Cir. 1981); *Odaers v. Ortho Pharmaceutical CorD.*, 609 F. Supp. 867 (E.D. Mich. 1985); *MacDonald v. Ortho Pharmaceutical Corr.*, 475 N.E.2d 65 (Mass. 1985); *Reaves v. Ortho Pharmaceutical Core.* 765 F. Supp. 1287 (E.D. Mich. 1991). *But cf. Henley v. FDA et al.*, No. CV 93— 5389, 1995 U.S. Dist. LEXIS 816 (E.D.N.Y. Jan. 17, 1995), (the court rejected plaintiff's claim that the FDA's warning label requirements for oral contraceptives are inadequate and misleading because they fail to warn women of the link between estrogen and cancer, particularly breast cancer.)

⁷³ Galen, *supra* note 69.

⁷⁴ *Id.* The debate on this issue continues, and in 1991, fertility scientists released a study challenging the result of the reports used in the Dalkon Shield litigation and asserting that the device does not increase the risk of pelvic infection. Lawrence K. Altman, *Study Finds*

pressure from the FDA, Robins discontinued sales of the product in 1974. Although the FDA would have permitted continued sales of the product if the firm maintained a user registry, the company declined this offer. Several years later, Robins informed women still wearing the device that they should have it removed.⁷⁵ In 1985, after paying about \$517 million for twenty—eight trial judgments and 9300 settlements, and still facing 327,014 timely—filed claims, Robins filed for bankruptcy.⁷⁶ Subsequently, American Home Products Corporation acquired A.H. Robins, and created a \$2.5 billion trust fund to compensate claimants for damages from the Dalkon Shield.⁷⁷

Unfortunately, the Dalkon Shield debacle was not an isolated event. The Copper 7, a seven-shaped TUD manufactured by G.D. Searle from plastic and copper, met a similar fate. Unlike the Dalkon Shield, the Copper 7 underwent extensive premarket testing by the FDA before its approval by the agency in 1974. Nevertheless, this TUD was also linked to increased incidence of PID which often leads to infertility. The Copper 7 generated hundreds of lawsuits before it was pulled from the market in 1985.⁷⁸

Doubt on Danger Arising from Use of IUDs, N.Y. TIMES, Apr. 15, 1991, at A1.

⁷⁵Altman, *supra* note 74.

⁷⁶Galen, *supra* note 69.

⁷⁷Altman, *supra* note 74. American Home Products attempted to expedite the compensation process by offering claimants non—negotiable settlements. If claimants refused this offer, the dispute would be settled in court. *Id.*

⁷⁸Galen, *supra* note 69, at 26, 27.

⁷⁹ *Id.*

⁸⁰ *Id.*

⁸ *Id.*

Plaintiffs' lawyers complained that G.D. Searle made many of the same mistakes made by A.H. Robins with the Dalkon Shield – the company proffered inflated efficacy claims, failed to warn about adverse side effects, and targeted the wrong population of women. According to the plaintiffs, G.D. Searle marketed the Copper 7 to young women who had never had children despite knowledge gained through both clinical studies and the Dalkon Shield cases that this population faced an increased risk of PID and should not use the IUD.⁷⁹ Nevertheless, plaintiffs' arguments seldom prevailed in court. Most of the cases brought against G.D. Searle were settled; most of those that went to trial were decided in the company's favor.⁸⁰

Plaintiffs' attorneys explained these results by noting the high evidentiary burdens faced by plaintiffs. In one case, Marder v. G.D. Searle, where seventeen Copper 7 users brought suit against the manufacturer, the claimants first had to demonstrate that the Copper 7 doubled the chances of causing PID, ectopic pregnancy, and perforation of the uterus before the judge would hear testimony about the plaintiffs' injuries. Because the jury could not decide whether the IUD increased by one hundred percent the risk of injuries, the judge directed a verdict for the company.⁸¹

Despite their legal victories, G.D. Searle decided to abandon the IUD market in the U.S. Women who still wanted

the product had to travel overseas.⁸² Plaintiffs' lawyers maintained that Searle's response was too drastic. They asserted that the company simply needed to modify its marketing strategy to focus on older women with children, and change its product labeling to express all of the risks.⁸³

Eventually, all the large firms manufacturing IUDs also bowed out, and for almost three years, only one TUD, Alza's Progestasert remained on the market. Alza maintained its market by first restricting its sales to private physicians and clinics that had used Progestasert in the past. Then, the company published an extensive patient information sheet, modeled after informed consent forms used in clinical trials. Before they could obtain a prescription for Alza's TUD, women had to sign the sheet, certifying that they had read and understood the risk information and had discussed any questions with a physician. With this consent system in place, the company lifted its restrictions on sales. While some patients filed suits against Alza irrespective of the informed consent program, the litigation was not of the magnitude that would bankrupt the company.⁸⁴ Alza's success no doubt stemmed in part from their monopoly over the

⁸² *Id.* Searle discontinued sales of the Copper 7 in Canada in 1987. See Morton Mintz, *The Selling of an IUD – Behind the Scenes at G.D. Searle During the Rise and Fall of the Copper 7*, WASH. POST, Aug. 9, 1988, (Health), at 16. In addition to seeking replacements overseas, other former IUD users took different approaches. According to one study, 45% of former IUD users chose sterilization for themselves or their partners; 40% used other birth control methods, and the remaining 15% used no method at all. Patricia Thomas, *Break Due After Decade of*

Drought: Contraceptives, MED. WORLD NEWS, March 14, 1988, at 49, 50.

⁸³ Galen, *supra* note 69, at 27.

⁸⁴ Thomas, *supra* note 82.

American IUD market until the approval of the ParaGard T380A in 1988.⁸⁵ Yet, even with the addition of this new IUD option, relatively few American women (about one to two percent of those of child-bearing age)⁸⁶ choose IUDs, especially in comparison to the number of users in other parts of the world.⁸⁷

At first glance, it seems hard to fathom how an FDA— approved device like the Copper 7 could encounter so many problems. Pharmaceutical companies seeking FDA approval of a new contraceptive must complete an extensive and expensive testing process. In 1986, the FDA estimated that this approval process would take about eight years, and cost approximately \$50 million.⁸⁸ Current estimates by pharmaceutical companies are even higher. According to a Tufts University study, development of a new chemical entity, from synthesis of the compound to market approval, takes about twelve years and as much as \$231 million in (pre—tax) 1987 dollars.⁸⁹ Nevertheless, testing does not necessarily reveal all of the risks of a product, in part because the

⁸⁵ *Id.* Following Alza's example, ParaGard also employs informed consent forms for users. See Mintz, *supra* note 82.

⁸⁶ Ortho 1993 Study, *supra* note 18.

⁸⁷ Altman, *supra* note 74. A 1987 study found that about 84.5 million women worldwide rely on IUDs for contraception, including approximately 11 million women in developed nations. *Id.*

⁸⁸ Galen, *supra* note 69, at 28.

⁸⁹ *rjew Chemical Entity R & D Costs Put at \$231 Mil. in Tufts Study, With About Half Attributed to Time Costs; Development Time Estimated at Twelve Years*, Food Drug and Cosm. L. Rep. (CCH), Pink Sheet, Apr. 23, 1990, at 13-14. For the Tufts study, Jospeh DiMasi, Ph.D., collected data from 12 American pharmaceutical companies. The \$231 million figure was derived by adding out—of—pocket costs with time costs, i.e., the calculation of interest lost on funds that might have otherwise been invested. *Id.*

FDA's determination depends upon the data the agency receives. This data is provided to the agency by both the manufacturers and the FDA'S advisory committees of medical experts. Critics suggest that this system allows for manipulation by industry; in fact, in some cases, the FDA medical experts have served as expert witnesses for industry in litigation.⁹⁰

Wells v. Ortho Pharmaceutical Corp. provides an example of the problems that may stem from the relationship between the FDA and industry.⁹¹ In 1982, Mary Maihafer sued Ortho Pharmaceutical Corp., on behalf of her daughter Katie Wells, claiming that Maihafer's post-conception use of Ortho-Gynol, the nation's largest selling spermicide, caused Wells' birth defects. Notably, only months before the suit was filed, the FDA'S Fertility and Maternal Health Drugs Advisory Committee (FMHDAC) had determined that spermicides were safe in such circumstances and that no warning was needed. Nevertheless, the trial judge in Wells held for the plaintiff, awarding her \$5.1 million in damages, which were later reduced to \$4.7 million on appeal.⁹²

The judge in Wells explained that his holding reflected his lack of faith in Ortho's expert witnesses and the FMHDAC report. More specifically, the judge noted that a key defense witness who had served on FMHDAC had failed to

⁹⁰Galen, *supra* note 69, at 28.

⁹¹Wells v. Ortho Pharmaceutical Corp., 615 F. Supp. 262 (N.D. Ga. 1985), *aff'd.*, 788 F.2d 741 (11th Cir. 1986).

⁹² Galen, *supra* note 69, at 28.

disclose to FMHDAC that he had previously been consulted by Ortho, thereby compromising the accuracy of the FMHDAC report. Ortho disputed the judge's conclusion,⁹³ and members of the National Institute of Child Health and Human Development (NICHD) decried the judge's failure to rely on scientific standards of proof.⁹⁴ Still, the court's findings reinforced the belief of many health advocates about the unacceptably close relationship between industry and the FDA.⁹⁵

Indeed, this distrust of the FDA's impartiality has inspired many women's health advocates to reject industry's proposals for a regulatory compliance defense whereby companies who obtained FDA approval for their product would be immune from suit. These advocates believe that litigation is the only effective means of modifying industry behavior. They support this claim by referring to the salutary effect that litigation has had on improving oral contraceptives. When the Pill first hit the market, women sued because of improper warnings and side effects. Today, oral contraceptives come in safer dosages with stricter warnings, and are rarely the subject of suit.⁹⁶

⁹³ *Id.* The lawsuit did not prompt the company to remove its product from the market. See Jeff Bailey, *Johnson & Johnson Denying Reports, Says it Won't Halt Sales of Spermicide*, WALL ST. J., May 21, 1986, at 5. ⁹⁴ James L. Mills & Duane Alexander, *Teratogens and Litogens*, 313 NEW ENG. J. MED. 1235 (1986). The FDA also maintained its initial position on the safety of spermicides, and perceived the Wells case as an aberration. See, *Data Do Not Support Association Between Spermicides, Birth Defects*, FDA DRUG BULL., Nov. 1986, at 21.

⁹⁵ Galen, *supra* note 69, at 28.

⁹⁶ *Id.* See also, *supra* note 72.

Whether or not lawsuits are an effective means of monitoring manufacturers, they are clearly not a thing of the past. The latest product under attack is Norplant, the hormonal contraceptive introduced by Wyeth—Ayerst in 1991. Implantation of Norplant requires an incision in the arm after numbing the area with a local anesthetic. Wyeth-Ayerst trained 28,000 physicians across the country in the insertion and removal of the rods. However, the FDA has not required all individuals who administer the contraceptive to undergo such training.⁹⁷

The popularity of Norplant quickly spread, and in its first year more than one million American women, and 2.5 million women worldwide, acquired the implant. Initial reaction to the drug was positive. However, within the past few years, television programs about women who suffered painful removals of the implant began airing, and the climate has changed dramatically. Over the past two years, several class actions have been filed across the country, and a federal judge may consolidate them into a single national claim.⁹⁸

The women suing Wyeth-Ayerst claim that removal of the implant can be lengthy and painful, and may leave ugly scars. Some physicians have corroborated these claims, noting that

⁹⁷Herman, *supra* note 2, at 13.

⁹⁸*Id.* As of February 1995, class actions against Norplant have been filed in California, Chicago and Texas. See, Bill Kisliuk, *Class Action Filed Against Manufacturer of Birth Control Device*, RZCORDER, Nov. 10, 1993, at 6; *Norplant Suit Given Class Status*, CHI. DAILY L. BULL., June 17, 1994, at 1; *Texas Lawsuit Filed by Norplant Users*, LIABILITY WK., Aug. 1, 1994.

the rods may be difficult to remove, requiring repeat visits, especially in instances where the rods have migrated.⁹⁹ In addition, the plaintiffs allege that the company failed to warn women of these possibilities and sold Norplant to physicians who received little or no training in removal.¹⁰⁰

Wyeth-Ayerst has responded to complaints by changing its product labeling to include a listing of some potential adverse effects. Nevertheless, the company is contesting the lawsuits, asserting that doctors who properly insert and remove the rods do not encounter any problems. Regardless of Wyeth-Ayerst's assurances, the demand for Norplant has decreased, and many women who had been using the drug without incident have requested premature removal, i.e., removal before the five—year period has elapsed. Still, unlike the IUD manufacturers in the 1980s, Wyeth-Ayerst has no plans to abandon its product. In fact, the company is planning to file a new drug application early this year for Norplant II, an implant of two rods that provides three years of contraceptive protection. In addition, Wyeth-Ayerst has a third product, a bio—degradable implant that requires no removal, in the final phase of clinical trials.¹⁰¹

Fears of lawsuits have extended beyond contraceptive manufacturers to material suppliers as well. Dow Corning, a

⁹⁹Serman, *supra* note 2, at 16. ¹⁰⁰*Id.*

¹⁰¹*Id.* In addition, Organon Int'l, a small Dutch firm that markets some of its contraceptive products abroad only, because of American litigiousness, is monitoring closely the Norplant situation. Organon has a one rod implant that lasts 2 years, and will base its decision to market its implant in the U.S. on the results of the Norplant suits. *Id.*

large chemical company, has reported that the firm will no longer manufacture materials used in contraceptives. According to the company's director of corporate and external communications, [w]e made a conscious decision to exit that entire market because of the litigious society.¹⁰²

In addition to discouraging new development among large pharmaceutical companies, litigation also negatively affects small research firms by dissuading insurance companies from covering contraceptive research and testing. Insurance companies have canceled liability policies for small biotechnology firms in response to the increase in lawsuits.¹⁰³ While such a blow may not be fatal to large firms with reserves to cover these potential costs, small firms cannot proceed with testing unless they can find doctors willing to assume liability or they can obtain local government insurance, available in some states. This situation places scientists in those states willing to insure research at an advantage over their colleagues from states that will not take on this burden. In one case, fertility scientists at the Research Triangle Institute in North Carolina who lost their insurance responded by sending their data on a long-lasting bio-degradable contraceptive implant to researchers at the University of California in San

¹⁰²*Id* at 13.

¹⁰³Michele Galen, *Insurance Crisis Curbs Contraceptive Development*, NAT'L L.J., Oct. 20, 1986, at 28.

Francisco because California officials agreed to indemnify researchers at the state university.¹⁰⁴

B. Politics

In addition to contending with the adverse effects of product liability litigation, drug companies are also dissuaded from contraceptive development because of negative political pressures. As Marc Deitch, medical director of Wyeth—Ayerst Laboratories, noted, [i]f you bring a new and novel treatment for depression [to the market] ... you're hailed as bringing a wonder drug. With contraception, you have to deal with social and religious issues that don't quite make it a level playing field in the United States.¹⁰⁵

Today, much of the political controversy in contraception surrounds mifepristone, a drug produced by French pharmaceutical company Roussel—Uclaf, and marketed as RU-486. While most of the hubbub stems from RU—486's use as an abortifacient, the vehemence of the debate demonstrates the political tension surrounding the development of drugs and devices which impact on reproduction.

Invented in 1982 by Roussel—Uclaf researcher Etienne—Emile Baulieu, RU-486 prevents pregnancy by blocking the action of progesterone in the uterus and ovary, causing early placental tissue to separate from the uterine wall. When followed by oral prostaglandins, which cause the uterus to

¹⁰⁴*Id.*

¹⁰⁵Berman, *supra* note 2, at 16.

contract and expel the placental tissue, RU-486 becomes, the best abortifacient ever devised.¹⁰⁶ This two-pill method also makes abortion a more private procedure that can be performed in any physician's office.¹⁰⁷ Because of its high cost and unpredictable effects on subsequent menstrual cycles, RU-486's use as a long-term contraceptive is still experimental.¹⁰⁸ Nevertheless, it appears to have great promise as a post-coital contraceptive alternative, i.e., a so-called morning after pill.¹⁰⁹

In 1983, the FDA first granted investigational new drug (IND) approval for mifepristone to the non-profit Population Council. At this time, the Council worked with the World Health Organization (WHO) and Roussel-Uclaf to determine the drug's effectiveness as a contraceptive. The last of these clinical trials was held in 1986, and in 1988, Roussel reported that it was not pursuing U.S. FDA approval for political reasons •

The company's reluctance to enter the American market was understandable considering the uproar that Roussel encountered in France when the firm initially offered RU-486 as an abortion alternative. After six years of testing on

¹⁰⁶Patricia Thomas, *French Abortifacient Still Too Hot for U.S.*, MED. WORLD NEWS, Mar. 14, 1988, at 63.

¹⁰⁷Jill Smolowe, *New, Improved and Ready for Battle*, TIME, June 14, 1993, at 48.

¹⁰⁸Thomas, *supra* note 106.

¹⁰⁹Allan Rosenfield, *Mifepristone (RU-486) in the United States: What does the Future Hold?*, 328 NEW ER3. J. MED. 1560 (1993). Moreover, the drug may also be useful in treating other conditions, including progesterone tumors of the breast, ovary, endometrium, and prostate, as well as Cushing's syndrome, a potentially fatal metabolic disorder. See Thomas, *supra* note 106.

⁰Thomas, *supra* note 106.

more than 17,000 women, the French government allowed RU—486 for public use in September 1988. The news unleashed a fury from the press, a deluge of letters from Roman Catholic doctors and a Church-sponsored protest in the streets of Paris. A month later, Roussel pulled the drug from the market in an effort to end the controversy.¹

Withdrawal of the product did not silence the debate. Indeed, doctors around the world were distressed by the pharmaceutical company's action. That same October, participants at a medical congress in Rio de Janeiro circulated a petition demanding that the French government reverse Roussel—Uclaf's decision. Within forty-eight hours, French Health Minister Claude Evin responded, ordering Roussel to resume distribution of RU-486.² By 1989, the drug was made available to all licensed abortion clinics and hospitals in France. Over the next three and a half years, 100,000 French women used the drug successfully. Indeed, only one serious incident was reported — a heavy smoker suffered a heart attack when trying to abort her thirteenth

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pregnancy.

Although the French government encouraged development of

RU-486, they placed restrictions on its use. French clinics may only prescribe RU—486 within the first trimester of pregnancy. Moreover, distribution of the drug requires four

¹Smolowe, *supra* note 107, at 50.

¹¹³*Id.* This case prompted the French government to prohibit the use of RU—486 for heavy smokers or women over 35, sub—populations who have higher risks of complications. *Id.*

clinic visits over a three—week period.⁴ Even with these conditions, French women have chosen RU—486 over surgery in eighty-five percent of the cases. The generally positive results in France led to the approval of RU—486 in Britain and Sweden, and testing of the drug in other countries, including India and China.⁵

Improvements in the administration of RU—486 in 1991 led to further controversy. Originally, women received the prostaglandins accompanying RU-486 in the form of an injection. However, in 1991, Roussel researchers found that using an oral prostaglandin marketed by American pharmaceutical company G.D. Searle was cheaper, more private and more effective. When Roussel-Uclaf balked at performing clinical trials for the new method because of political pressures, the French government again required the firm to continue testing and also agreed to defray insurance costs.⁶ Like the managers at Roussel, executives at G.D. Searle were uncomfortable with their connection to RU—486. As a result, the company wrote a letter to the editor of The Wall Street Journal in March 1993 stating, [i]t is not Searle's

~⁴*Id.* at 51. The first visit includes a gynecological exam to determine the stage of pregnancy, as well as a counseling session on abortion. After a one—week reflection period, patients return to the clinic to obtain the RU-486 tablets, sign a government form requesting abortion, and complete a Roussel-Uclaf consent form indicating knowledge of the risks to the fetus if the abortion is not carried to completion (though as of yet, no birth defects have been found in the small number of babies born to women who took the drug). After 48 hours, the patient must go back to the clinic for prostaglandins. Eight to ten days later, she has a final follow-up visit to ensure that no part of the egg remains in her body. *Id.*

~⁵*Id.* at 50.

intention or desire to become embroiled in the abortion issue. 117

Despite its increasing popularity abroad, domestic politics have slowed the entrance of RU-486 into the U.S. In June 1989, the FDA imposed an importation ban on the drug, partly in response to letters from influential anti-abortion Congressmen.⁸ Noting that several IND applications for research on RU-486 had been approved, the agency claimed that the ban only prohibits importation of RU—486 for personal use. Moreover, the FDA insisted that the ban had been imposed for safety reasons, i.e., to ensure that RU—486 was not brought into this country surreptitiously for use as an abortifacient without proper medical supervision.⁹

Despite these claims, the agency's actions caused an uproar among researchers who relied on the drug for their studies. These scientists suggested that FDA policy limiting access to RU-486 hindered their progress, and made Roussel—Uclaf reluctant to work with them.²⁰ The FDA importation ban also upset feminist and reproductive rights groups seeking access to the drug for individual use. Congressional hearings on the issue were held, but no change was made in

~~~<sup>7</sup> *Id.* at 51.

<sup>8</sup>Denise Chicoine, *RU-486 in the United States and Great Britain, A*

*Case Study in Gender Bias*, 16 B.C. INT'L & COMP. L. REV. 81, 94-95 (1993). Within three weeks of receiving angry letters from Reps. Robert

K. Dornan (R-CA), Henry Hyde (R-IL), and John LaFalce (D-NY), and Sen.

Jesse Helms (R—NC), requesting restrictions on access to RU-486, the FDA Commissioner issued the importation ban. *Id.*

<sup>119</sup>*FDA Did Not Intend to Halt RU 486 Research, Agency Testifies; 10 IND Applications Approved for Research*, Food Drug Cosm. L. Rep. (CCH), Blue Sheet, Nov. 21, 1990, at 6—7.

official policy.<sup>21</sup> In addition, the ban was challenged unsuccessfully in the courts in 1992 by a pro—choice group called Abortion Rights Mobilization (ARM).<sup>22</sup>

Some changes in policy have occurred with the change in administration, but progress has been slow. As one of his first official acts, President Clinton issued a memorandum on January 22, 1993, directing the Department of Health and Human Services (HHS) to consider the testing and licensing of RU-486 in the U.S. In April 1993, negotiations began between representatives of the FDA, Roussel—Uclaf, and the Population Council. The talks culminated more than one year later in Roussel—Uclaf's donation of its patent rights for RU-486 to the Population Council, with the understanding that the Council would take the steps necessary to bring the drug to market.<sup>23</sup> By this time, several state legislatures had volunteered their states as test sites.<sup>24</sup>

<sup>21</sup>Chicoine, *supra* note 118, at 98. In February 1992, Representative Ron Wyden (D-OR) introduced the RU-486 Regulatory Fairness Act in Congress. The goal of the measure was to make the FDA Import Ban ineffective as to RU-486. Senator Alan Cranston (D-CA) subsequently sponsored the same bill in the Senate. *See also*, 138 CONG. REC. S2337 (daily ed. Feb. 26, 1992).

<sup>22</sup>Smolowe, *supra* note 107, at 51. When ARM helped Leona Benten a pregnant 29 year—old social worker from California, obtain a dose of RU— 486 in England and attempt to bring it into the US, American custom officials seized the pills. The case was eventually heard by the Supreme Court. The Court refused to order the government to return the pills, and Benten had a surgical abortion. *Leona Benten v. David Kessler*, Comm'r. FDA, 112 5. Ct. 2929 (1992) (per curiam). <sup>23</sup>*Roussel Uclaf Donates U.S. Patent Rights for RU-486 to Population Council*, BBS NEWS (U.S. Dep't of Health and Human Servs., Wash., D.C.), May 16, 1994. BBS's announcement of the donation quoted BBS Sec'y Donna Shalala stating, [w]e strongly believe that women in America should have access to the full range of safe and effective alternatives to surgical abortion ... [nevertheless] the donation does not mean RU—486 has been approved for use in the United States. *Id.* Furthermore, an accompanying BBS fact sheet commented on the strict distribution rules in effect in the countries where RU-486 is currently available, noting that such conditions would also apply in the US. *Mifepristone (RU-486)*:

Responsibility for making RU-486 available in this country now lies with the Population Council.<sup>125</sup> The Council must find a U.S. manufacturer before it can apply for a new drug application with the FDA.<sup>126</sup> Although extensive trials have already been performed worldwide, including a multi-center study by WHO, the FDA has predicted that the approval process will take two to three years.<sup>127</sup> One option the Council is considering is a proposal by RU—486 inventor Baulieu to establish a non—profit foundation whose sole function is to manufacture and distribute RU-486 worldwide. Such an organizational structure would insulate the RU—486 producer from political pressures by making boycott threats irrelevant.<sup>128</sup>

While RU-486 has captured national attention as an abortifacient, the National Academy of Science's Institute of

*Brief Overview*, BBS F~T SHEET (U.S. Dep't of Health and Human Servs., Wash., D.C.), May 16, 1994.

<sup>124</sup>Smolowe, *supra* note 107, at 49.

<sup>125</sup>David Van Biema, *But Will it End the Abortion Debate?*, TIME, June 14, 1993, at 52, 53. Although President Clinton has expressed some interest in promoting pro—choice policies, the FDA has not rescinded its ban on importation of RU—486 for personal use. See, Susan Jacobs, *Hurry Up and Wait Characterizes RU—486 Status Today*, 85 J. NA~L CA1~ER INST. 1110, 1111 (1993).

<sup>126</sup>Van Biema, *supra* note 125. <sup>127</sup>Rosenfield, *supra* note 109.

<sup>128</sup>Van Biema, *supra* note 125, at 53. There is some irony in the vehemence of the protests surrounding RU-486, the drug that was intended in part to end the protests. Nevertheless, activists on both sides of the RU-486 debate are determined that their respective views will prevail. Proponents of RU-486 are hoping that the privacy of the new method will encourage physicians who have stopped performing abortions for fear of political consequences to resume the practice. We will not allow anti—choice zealots to deny RU—486 to American women, said Pamela Maraldo, president of Planned Parenthood Fed'n of America. In contrast, anti-abortion activists have vowed to find the doctors dispensing RU—486 and picket them. As Rev. Keith Tucci of Operation Rescue Nat'l noted, [w]hen they invent new ways to kill children, we will invent new ways to save them. Smolowe, *supra* note 107, at 49, 53.

Medicine is encouraging the further testing of mifepristone both as a long-term contraceptive like the birth control pill, and as a post-coital method. Preliminary results from studies of the latter use appear particularly promising. Mifepristone seems to be more effective than the current post-coital options, and unlike the other methods currently available, it involves only a single dosage.<sup>29</sup>

Of course, marketing RU—486 for use as a post-coital contraceptive may not mitigate any of the controversy surrounding the drug. Indeed, the morning after method most frequently used today, which consists of highly concentrated doses of female hormones, has also been the subject of political disputes. The post-coital contraceptive, first described in Canadian and Dutch studies twenty years ago, works by interfering with normal reproductive processes either to prevent fertilization or to stop fertilized eggs from implanting in the uterus.<sup>30</sup> Such drugs are widely available in Europe, and according to experts, the products' accessibility abroad helps account for those countries' lower unplanned pregnancy rates.<sup>31</sup>

In contrast, in the United States, this form of birth control remains somewhat of a secret, mostly because no drug has been approved by the FDA for post-coital use.<sup>32</sup> Ovral,

<sup>29</sup>*Potential Benefits of RU 486, Other Antiprogestins Are Extensive*

(Inst. of Medicine, Wash., D.C.), Sept. 7, 1993. <sup>30</sup>Hoffman, *supra* note 26, at 12—13.

<sup>31</sup>*Id.* at 14.

<sup>32</sup>*Id.* The FDA has published guidelines regarding the post-coital use of DES. *See, infra* p. 52.



manufactured by Wyeth—Ayerst, is the most commonly used post—coital contraceptive in this country. Ovral was approved as a long—term oral contraceptive in 1968, and no company has applied for permission to promote or label it for any other use.<sup>133</sup> As a result, while Ovral is widely prescribed on college campuses, and routinely prescribed to rape victims in hospital emergency rooms for post-coital use, many physicians are unfamiliar with it. Moreover, without official federal approval, Ovral cannot be dispensed for post—coital use at the four thousand federally funded Title X clinics. Thus, these clinics' four million (largely indigent) patients have no access to the product.<sup>134</sup>

Manufacturers' reluctance to market a morning after pill may reflect popular ambivalence about post-coital intervention. People disagree about whether a drug taken after intercourse is more akin to contraception or abortion; individual beliefs on this question reflect different views on when conception begins.<sup>135</sup> To further complicate the matter, a woman takes a post—coital contraceptive even before she is certain that fertilization has occurred. Finally,

<sup>133</sup> *Id.* at 30.

<sup>134</sup> *Id.* at 14.

<sup>135</sup> *Id.* at 30. The National Right to Life Committee has defined conception as fertilization, i.e., as contact of spermatozoon with ovum. This perception is shared by some Catholic hospitals which refuse to prescribe morning after pills. Other groups, including the American College of Obstetricians and Gynecologists, consider implantation, rather than fertilization, as conception. *Id.* See also, Brownfield v. David Freeman Marina BosD., 208 Cal. App. 3d 405 (1989), (when a rape victim sued a Catholic hospital for refusing to prescribe a post-coital contraceptive, the state appellate court held for the plaintiff, finding that the method is preventive, and not equivalent to abortion).

there is some resistance to the idea that such a drug enables women to eliminate the consequences of accidents.<sup>136</sup>

In addition to inspiring ethical debate, the morning after pill faces other problems. Industry representatives note that while clinical trials and agency review for a new drug takes about twelve years and more than \$231 million, obtaining approval for a supplementary use could take five more years and additional tens of millions of dollars.<sup>137</sup> Moreover, once the patent on a drug expires, the product may be copied by other firms who did not have to make the initial multi-million dollar investment. Pharmaceutical firms would have particular difficulty recouping their investment for products intended for post-coital use because women who use them often do so only once in their lifetime.<sup>138</sup>

Pharmaceutical firms' may also be dissuaded from seeking approval for post-coital methods by the negative reactions that such products have inspired from women's groups. In 1975, the National Women's Health Network (NWHN) demonstrated against the FDA, claiming that the agency had applied insufficient scrutiny to high estrogen regimens.<sup>139</sup> In

<sup>136</sup> *Id.* at 14. Felicia Stewart, author of Contraceptive Technology, has

expressed concern that much opposition to post-coital drugs stems from the view that women should not be able to undo their mistakes. In response to individuals who share that perspective, she states:

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t's only in the area of sex that we get involved in the ethics of promoting risk-taking, the idea that we should withhold information or devices because we don't want people to need them. Would you make the same argument about cholesterol drugs? Saying, if we give people a drug that will reduce cholesterol, they won't be as likely to exercise and eat properly like they really should?

*Id.* at 15.

<sup>137</sup> *Id.* at 30.

<sup>138</sup> *Id.*

<sup>139</sup> *Id.*

1980, NWHN organized a letter-writing campaign to demand that the FDA conduct safety studies on post-coital estrogens before releasing the drugs to the public, and the network maintains its wariness towards hormonal products to this day.<sup>40</sup> Even proponents of post-coital contraceptives have expressed concern with the products currently available. Their complaints focus on the drugs' side effects and limited efficacy, as well as their fear of women's reliance on a method that does not protect them from HIV and other STDs. Because of these shortcomings, many clinics require informed consent forms before dispensing post-coital contraception, viewing the drugs only as an emergency method.<sup>41</sup>

While abortion is currently the big political issue plaguing contraceptive development, political controversies have long accompanied advances in birth control. When the Pill was first distributed in 1960, the FDA was quick to distance itself from any position on the morality of preventing childbirth. In press statements issued at the time, the agency asserted that neither the FDA nor the Department of Health, Education and Welfare advocate or discourage the use of contraceptive products. ... We are in all aspects neutral on this subject.<sup>42</sup> As it turned out, the FDA'S circumspection was misguided. The Pill did not inspire the expected outrage from parties morally opposed to

<sup>40</sup> *Id.*

<sup>41</sup> *Id.* at 15.

<sup>42</sup> Suzanne White, FDA's Approval of the Contraceptive Pill 22 (July 1992) (draft, on file with the Food and Drug Administration).

the prevention of childbirth.<sup>143</sup> Instead, its development provoked charges that the FDA was unconcerned with women's health.

For years, feminists had championed the development of a birth control pill that would put reproductive choices in the hands of women. Yet soon after the Pill appeared on the market, it inspired criticism from these same groups. Within the first few years of the Pill's distribution, researchers recognized that the original Pill composition provided an overdose of hormones and caused unnecessary side effects. Nevertheless, doctors continued to prescribe it, and feminists believed these actions demonstrated physicians' callousness towards women.<sup>144</sup>

Public concern about the safety of the Pill increased over time. In 1970, Senator Gaylord Nelson (D—WI) of the Senate Select Committee on Small Business began Congressional hearings on the safety of the Pill, as part of his larger investigation of the pharmaceutical industry.<sup>145</sup> Simultaneously, women were mobilizing to educate and protect themselves and others. In 1969, Barbara Seaman published The Doctor's Case Against the Pill. During this same period, the first editions of Our Bodies. Ourselves also became available. In addition, in 1975, Barbara Seaman and Belita Cowen established the National Women's Health Network (NWHN) as a full-time feminist health lobby in Washington, D.C.

<sup>143</sup> *Id.*

<sup>144</sup> Bilts, *supra* note 13, at 70.

<sup>145</sup> CARL DJERASSI, THE POLITICS OF CONTRACEPTION 91—93 (1979).

NWHN remains a prominent voice in health politics, and continues to caution against hormonal methods of birth control, advocating instead the use of barrier methods and spermicides 146

The controversy surrounding Depo Provera provides yet another example of the politicization of birth control. In 1974, the FDA proposed approving Depo Provera as a contraceptive. This proposal followed years after Depo Provera was approved as a cancer drug in this country, and after it had proved to be a safe and effective contraceptive in other nations.<sup>147</sup> The FDA'S proposal inspired a strong adverse reaction from feminist groups who feared unwanted side effects from the drug. This feminist campaign led the FDA to defer its decision until 1978.<sup>148</sup> That year, the FDA denied Upjohn's application for approval, citing clinical tests that showed that the drug caused tumors in dogs.<sup>149</sup> The FDA's action upset manufacturers who felt that the agency had cowed too easily to political pressure over a drug that the agency had initially agreed was safe and effective.<sup>150</sup> Although physicians continued to prescribe Depo Provera for its unapproved use as a contraceptive,<sup>151</sup> pharmaceutical companies viewed the FDA's action as a major deterrent to contraceptive research. These feelings were reinforced in

<sup>146</sup>Bilts, *supra* note 13, at 70.

<sup>147</sup>*Id.*

<sup>148</sup>*Id.*

<sup>149</sup>*Advisory Panel Recommends Approval for Depo Provera*, *supra* note 28.

<sup>150</sup>*Id.*

<sup>151</sup>Kristin Neil, *The Depo Provera Battle*, THE NETWORK NEWS (Nat'l Women's

Health Network, Wash., D.C.), Sept./Oct. 1992, at 5.

1985, when Upjohn reapplied for approval, and their application was again denied.<sup>152</sup>

In June 1992, an advisory committee of the FDA recommended approval of Depo Provera.<sup>153</sup> Several groups testified against this decision, including the National Women's Health Network, the National Black Women's Health Project, the National Latina Health Organization and Women's Economic Equity. These organizations presented studies linking long-term use of the drug to cancer and osteoporosis, and expressed concerns as well about Depo Provera's short-term side effects.<sup>154</sup> Despite the opposition, the FDA approved Depo Provera for contraceptive use in 1992, eighteen years after the agency had initially proposed approval.<sup>155</sup>

Alongside the traditionally controversial issues associated with contraception, i.e., abortion, sexual mores and women's health concerns, a fairly new debate has arisen concerning issues of social control. This debate focuses primarily on the use of Depo Provera and Norplant, long-term contraceptives that require little user participation. Notably, the women's groups that opposed Depo Provera for health reasons also feared that the drug would be used for custodial convenience.<sup>156</sup> In other words, they worried that

<sup>152</sup>Bilts, *supra* note 13, at 70.

<sup>153</sup>*Advisory Panel Recommends Approval for Depo Provera*, *supra* note 28. The Advisory Panel's recommendation followed WHO's 1991 conclusions that studies describing the negative effects of Depo Provera on dogs are inapposite because of the physiological differences between dogs and women. *Id.*

<sup>154</sup>Neil, *supra* note 151. <sup>155</sup>Goldberg, *supra* note 16, at 24. <sup>156</sup>Neil, *supra* note 151.

because of its high efficacy rate as a contraceptive, Depo Provera would be prescribed for women in prison and mental institutions without regard for its effects on these women. Because of its similarly high rate of efficacy, the same concerns about institutional use have also been associated with Norplant.

In fact, because one insertion of Norplant lasts for five years (as opposed to Depo Provera where each injection lasts only three months),<sup>57</sup> this drug has served as the focal point for much of the discussion about the use of contraception for social control. Only a few weeks after Norplant's approval, an editorial in *The Philadelphia Inquirer* suggested that Norplant could be a useful tool for reducing the underclass.<sup>58</sup> While the newspaper later apologized for its statements, the editorial apparently struck a chord in many people concerned about the increasing social and financial costs of caring for poor and abused children.<sup>59</sup> From 1991 through 1992, thirteen state legislatures sponsored twenty bills offering more public assistance to women on welfare who use Norplant. In 1993, seventeen such measures were proposed in ten states, and at least two were enacted.<sup>60</sup> In California, the governor took

<sup>57</sup>Goldberg, supra note 16, at 24.

<sup>58</sup>Stacey L. Arthur, *The Norplant Prescription: Birth Control, Woman Control or Crime Control?*, 40 UCLA L. REV. 1, 4 (1992).

<sup>59</sup>Lynn Smith & Nina J. Easton, *The Dilemma of Desire*, L.A. TIMES, Sept.

26, 1993, (Magazine), at 24.

measures to make the contraceptive easily available to teenagers and female drug abusers.<sup>'61</sup>

The controversy surrounding the potential for Norplant's societal use came to a head in February 1991, when a California judge required use of Norplant as part of a criminal sentence. In People v. Johnson, Judge Howard Broadman ordered the defendant, a convicted child abuser to have Norplant inserted for three years as a condition of her probation.<sup>'62</sup> While Johnson initially accepted this condition, one week later she moved for reconsideration and modification of the order. Johnson's motion was denied and she appealed.<sup>'63</sup> Her appeal garnered national attention, as well as the support of civil and reproductive rights groups, including the American Civil Liberties Union (ACLU) and Planned Parenthood, who considered the order an unconstitutional infringement of Johnson's freedom. Before the appeal was argued, Johnson violated her probation by testing positive for cocaine on three occasions. Based on these violations, the court rescinded the probation order, sentenced Johnson to five years in prison, and dismissed as moot her appeal of the conditions of her probation.<sup>'64</sup>

A similar order was made by a Nebraska court in April 1991, when a defendant was required to use Norplant as condition of her probation after she allowed her boyfriend to

<sup>'61</sup> Arthur, *supra* note 158, at 5.

<sup>'62</sup> *Id. citing People v. Johnson* (Cal. Super. Ct. Tulare County 1991) (No. 29390).

<sup>'63</sup> Arthur, *supra* note 158, at 16, 17.

<sup>'64</sup> *Id.* at 18.



murder her six—month old son.<sup>165</sup> In this case, the order was later modified to allow the defendant to use any form of birth control.<sup>166</sup> This modification essentially made the order unenforceable. In light of the failure rates of contraceptives, the court would not be able to assess the defendant's compliance. Judges have also mandated Norplant use in other states, including Texas, Florida and Illinois.<sup>167</sup>

Some commentators see both the legislative proposals and the judicial orders as practical means of reducing social welfare costs while protecting children, born and unborn, from abuse.<sup>168</sup> Still, civil and reproductive rights groups have been quick to express their opposition, describing the measures as discriminatory and comparing them to unlawful forced sterilization.<sup>169</sup> The American Medical Association (AMA) has also opposed requiring the use of Norplant. Representatives from the AMA stated, [t]here is not sufficient evidence to demonstrate that long—acting contraceptives are an effective social response to the problem of child abuse.<sup>170</sup>

The controversy about the prescription of Norplant has continued unabated. In 1993, black religious leaders opposed a proposal to offer Norplant in Baltimore's inner—city schools where most students were black, describing the plan

<sup>165</sup> *Id.* at 6, 21, *citing* State v. Carlton. (Neb. County Ct., Lincoln County 1991)(No. CR90—1937).

<sup>167</sup> Smith & Easton, *supra* note 159.

<sup>168</sup> *Id.*

<sup>169</sup> *Id.*

as a form of social engineering.<sup>71</sup> Concerns about discriminatory prescription of the implant have led the Los Angeles Regional Family Planning Counsel to train counselors to consider their own biases before recommending Norplant to teenagers or drug abusers.<sup>72</sup> Moral issues aside, public health experts have found that low-income minority women may be particularly poor candidates for Norplant because of health reasons. Poor women often have health conditions like obesity, high blood pressure and diabetes, which make Norplant a risky choice. Moreover, black women are especially prone to cervical cancer and the warning signs of irregular bleeding may be masked by the use of Norplant.<sup>73</sup> Generally, some commentators see offering women Norplant as tantamount to increasing their chances of succeeding in life, by preventing the problems of unwanted pregnancy. Others feel that advocating Norplant encourages irresponsible promiscuity and/or implies that women cannot, and should not be permitted to, control their own sexuality.

In addition to expressing concern that contraceptives are used as a form of social control, some experts believe that the snail's pace of contraceptive research reflects gender bias.<sup>74</sup> One commentator noted that it was not until 1937 that the AMA passed a resolution declaring the medical profession's affirmative duty to inform women about

<sup>71</sup>Mimi Hall, *Norplant Causes Furor in Baltimore*, USA TODAY, Feb. 9, 1993, at 3A.

<sup>72</sup>Smith & Easton, *supra* note 159. <sup>73</sup>*Id.*

<sup>74</sup>Chicoine, *supra* note 118, at 100, nn.150—151.

contraception.<sup>175</sup> Moreover, some people believe that the delays in contraceptive development are symptomatic of a general disregard for women's health issues in this country. One expert expressing the low priority given to women's health issues, suggested that the systematic exclusion of women from health care training until late in this century has adversely affected research and treatment of women's health concerns in the U.S.<sup>176</sup>

Attributing the paltry amount of funding for contraceptive research to societal indifference to women's health concerns, experts cite studies which indicate that federal money spent on female sterilization has far outweighed the funding devoted to the development of new modes of contraception.<sup>177</sup> As late as the 1980s, practitioners provided accounts from communities where tubal ligations were routine for all woman at age twenty—one because the operations were covered by Medicaid.<sup>178</sup> Finally, some commentators reduce much of the controversy surrounding new methods of contraception, as well as the delays in development, to the fact that most of the beneficiaries of these products are women, while most of the decision-makers,

<sup>175</sup>White, *supra* note 142, at 25. In addition, the issue of individuals' right of access to contraception has been the subject of much litigation. *See, e.g., Griswold v. Connecticut*, 381 U.S. 479 (1965); *Eisenstadt v. Baird*, 405 U.S. 438 (1972); and *Carey v. Population Services Int'l*, 431 U.S. 678 (1977). However, this debate over constitutional rights is beyond the scope of this paper.

<sup>176</sup>Chicoine, *supra* note 118, at 100 nn.150—151.

<sup>177</sup>*Id.* at 101 n.155. The author also reports that hysterectomies are the most commonly performed operation of the 20th century and have been found to have been unnecessary in 60% of the cases. *Id.* at 101. <sup>178</sup>*Id.* at 101 n.156.

from politicians to regulators to pharmaceutical company executives, are men.<sup>179</sup>

### C. Testing

In addition to the legal and political problems hindering the industry's development of new forms of contraception, there are practical obstacles as well, including strict clinical testing requirements. According to Roderick L. Mackenzie, former president of Ortho Pharmaceutical Corp., today, it would take a study of 50,000 women over ten years to develop a contraceptive comparable to the Pill or IUD.<sup>180</sup>

To obtain new drug approval in the United States, a pharmaceutical company must complete a several stage process. The process begins with preclinical investigations and animal testing, followed by clinical testing in several phases with increasingly larger population samples, and ends with final review by the FDA.<sup>181</sup> Traditionally, the FDA does not allow contraceptive manufacturers access to any of the short cuts which may be permitted for manufacturers of drugs created to treat disease, because birth control products are intended

<sup>179</sup>*Id.* at 111.

<sup>180</sup>Herman, *supra* note 2, at 14.

<sup>181</sup>Chicoine, *supra* note 118, at 87. There are three main phases of testing: the goal of Phase I testing is to collect basic data on the safety of the new drug by conducting tests on a small group (100 or fewer) of healthy subjects; in Phase II, researchers focus on the efficacy and short-term side effects of the new drug by conducting tests on several hundred patients who are divided into treatment and control groups; Phase III involves thousands of patients over a period of years, and is intended to establish the drug's effectiveness, its long-term side effects, and its optimal dosage levels. *Id.* at 87 n.41.

for use in healthy people.<sup>182</sup> As noted by Carl Djerassi, the scientist who first synthesized the Pill in 1951, [c]ancer patients are willing to tolerate side effects because they hope the drugs will save their lives. People do not, however, consider unwanted pregnancies a disease and are not prepared to take risks.<sup>183</sup>

Perhaps more interesting than the American process itself is how it compares to the system used in Great Britain, a country with a shorter lag time for drug development and more contraceptive choices, yet similar morbidity and mortality rates as the U.S.<sup>184</sup> The preclinical testing phase in the U.S. takes twice as long as the one in Britain, mostly because the FDA requires submission of both domestic and foreign data for preclinical and clinical trials, while Britain's Committee on the Safety of Medicines (CSM) permits the use of foreign data alone.<sup>185</sup> The FDA is a more reactive agency than CSM, and unlike CSM, which is considered to act independently of political leaders or pharmaceutical companies,<sup>186</sup> the FDA will not begin evaluating a drug until a manufacturer submits a new drug application for approval. While critics describe the FDA as more subject to political pressures than its British counterpart, the flip

<sup>182</sup>Elizabeth Sweetenham, *Fear of Litigation Is Hindering New Contraceptive Research*, OBSERVER, June 5, 1994, at 6.

<sup>184</sup>Chicoine, *supra* note 118, at 91.

<sup>185</sup>*Id.* at 87.

<sup>186</sup>*Id.* at 88. However, financial links have been found between some members of the Committee and the pharmaceutical companies. *Id.* n.50.

side of this position is that the American agency feels a greater sense of government accountability.<sup>187</sup>

As a consequence both of this sense of duty, and the American tort liability system, the main difference between the American and British approval process is that the FDA focuses on premarket screening, while CSM relies on post-market surveillance. FDA reviewers work under the premise that they have little or nothing to lose by refusing, or at least delaying, the grant of a license, and everything to lose if [al thalidomide [is approved]].<sup>188</sup> In contrast, British regulators concentrate on monitoring the effects of a product after it has been approved. CSM policy presumes that serious rare side effects will not appear until a large population has used a drug. Moreover, Britain's nationalized health care program and the size of its population facilitate post—market surveillance because of the ease in tracking the activities of each doctor and patient in the system.<sup>189</sup>

Although the FDA is primarily a reactive organization, in one notable instance, the regulation of diethylstilbestrol (DES) as a post—coital contraceptive, the agency adopted a pro-active approach similar to the one associated with Britain's CSM. When DES was initially approved as safe for use in human medicine in 1941, the FDA did not demand any proof of safety or efficacy.<sup>190</sup> Between 1945 and 1955, DES

<sup>187</sup> *Id.* at 88—89.  
<sup>188</sup> *Id.* at 88—89 n.57.  
<sup>189</sup> *Id.* at 88.

<sup>190</sup> P.B. Butt, *DES: FDA and the Law*, in ORIGINS OF HUMAN CANCER, BOOK C: HUMAN RISK ASSESSMENT, 1651 (B.B. Hiatt et al. eds., 1977).

was commonly prescribed for prevention of miscarriage.<sup>91</sup> By 1962, the Food, Drug, and Cosmetic Act of 1938 had been amended to require that drugs be tested for efficacy. Within the next few years, studies were released linking the use of DES during pregnancy to cancer, both in the women who used the drug and their female offspring.<sup>92</sup> Although the FDA responded to these reports by demanding that DES be labeled as inappropriate for use during pregnancy,<sup>93</sup> physicians were still prescribing the drug for its unapproved use, as a post-coital contraceptive.<sup>94</sup>

For the reasons described above,<sup>95</sup> manufacturers are reluctant to pursue new drug applications (NDAs) for post-coital methods of contraception. Thus, in 1973, the FDA decided to initiate its own evaluation of DES for post-coital use. Working with its Obstetric and Gynecological Advisory Committee, the agency reviewed the available scientific evidence. In September 1973, the FDA published a proposed rule in the Federal Register, establishing safety and efficacy parameters for DES usage, and soliciting comments from interested parties.<sup>96</sup> One and half years later, in

<sup>91</sup>*Phase II Trials of Taxol, Ifosfamide for Recurrent Vaginal Clear Cell Cancer in DES-Exposed Needed*, Food Drug Cosm. L. Rep. (CCH), Blue Sheet, Apr. 29, 1992 at 2—3.

<sup>92</sup>Hutt, *supra* note 190, at 1653.

<sup>94</sup>Letter from Peter Barton Hutt, Partner, Covington & Burling, to Philip A. Corfman, M.D., Supervisory Medical Officer for Fertility and Maternal Health Drugs, FDA 5, (Nov. 6, 1992) (on file with Covington & Burling). Prescribing an approved drug for an unapproved use is lawful according to the FDA'S interpretation of the Food, Drug, and Cosmetic Act. *Id.*

<sup>95</sup>See discussion of post-coital contraception, *supra*, pp. 38-40. <sup>96</sup>Letter from Peter Barton Butt, *supra* note 194, at 6.

February 1975, the agency issued a final rule stating that the FDA would permit marketing of DES as a post-coital contraceptive by any applicant who obtains an approved abbreviated NDA.<sup>197</sup> Although no pharmaceutical company submitted an NDA for the post-coital use of DES, the FDA'S rule-making process allowed for comment by physicians and consumer groups,<sup>198</sup> and provided guidelines for physicians who continued to prescribe the product.<sup>199</sup>

The FDA's activist approach in the DES case remains the exception. Indeed, in many instances, the FDA's strict requirements deter drug manufacturers from marketing their products in the U.S. As Richard Lincoln of the AGI states, [t]he situation we are getting into is funding research that is being done in other countries for products that will be used in other countries that will never be approved by the U.S. Food and Drug Administration.<sup>200</sup> In other cases, the FDA'S approval process simply serves to delay American access to products long available in Europe. One example of this phenomenon is provided by Ortho Pharmaceutical Corp. 's ORTHOCEPT (desogestrel/ethinyl estradiol), which was first marketed in the U.S. in January 1993, one month after the

<sup>197</sup>*Id.* For a manufacturer to obtain NDA approval, the company had to require written informed consent from patients before distribution of the drug. Moreover, the product had to be packaged specially for postcoital use, and the labeling had to explicitly list any and all risks. *See, Butt, supra* note 190, at 1656. The use of DES was so controversial that even this narrow approval provoked the Senate to propose legislation further limiting access to DES. Ultimately, Congress failed to pass any measure regulating DES for post—coital use. *Id.*

1984Q Fed. Reg. 5351 (February 5, 1975).

<sup>199</sup>Letter from Peter Barton Butt, *supra* note 194, at 6. <sup>200</sup>Galen, *supra* note 69.



company obtained FDA clearance. In Europe, this product has been available since 1981, and is currently the most widely-prescribed oral contraceptive <sup>201</sup>

The FDA's testing requirements have proved an obstacle to other manufacturers as well. Lamberts, Ltd., the manufacturer of the cervical cap, had to overcome several hurdles before its product could be offered in this country. In 1976, Congress responded to the Dalkon Shield tragedy by increasing FDA regulation of medical devices. Based on their long history of use in this country, condoms and diaphragms were subject to grandfather clauses and did not have to undergo agency evaluation. However, the FDA determined that the cervical cap fell under the new regulations.<sup>202</sup> The FDA'S determination ignored the fact that the cap has been in use in some form since the 19th century, and that it has been used worldwide in its modern incarnation for about sixty years. Indeed, apparently unbeknownst to the FDA, the cap had been already available in the U.S. through mail order.<sup>203</sup>

Initially, Lamberts, Ltd., a small English company, refused to comply with the new testing requirements. For a company of its size, the investment necessary to meet FDA standards was not economical. Consequently, despite its past safety record, the cervical cap was prohibited from sale in the U.S. Finally, in 1985, under pressure from women's

<sup>201</sup> *Ortho Expands Its Oral Contraceptive Line: Introduces ORTHO-CEPT and*

*Brings Europe's #1 Birth Control to the U.S.* (Ortho Pharmaceutical

Corp., Raritan, N.J.), Jan. 18, 1993.

<sup>202</sup> Thomas, *supra* note 82, at 62.

groups, the FDA permitted Lamberts, Ltd. to perform abbreviated toxicity tests and the NICHD sponsored a study comparing the cap to the diaphragm.<sup>204</sup> Three years later, in May 1988, the FDA offered approval of the cervical cap with the following conditions: it may be prescribed only to women with normal Pap tests, and cap users must return to their physician after the first three months for a Pap test. Moreover, the FDA demanded that the manufacturer state the risk of toxic shock syndrome on the product label, and conduct post-market studies on the link between the product and cervical cell changes that may precipitate cervical cancer.<sup>205</sup> Despite these conditions and the expense of the approval process, the company was optimistic about its long—awaited entry into the American market.<sup>206</sup>

The cervical cap example highlights the cost/benefit analysis that pharmaceutical firms must perform before deciding whether to undertake the expense of seeking approval for contraceptives in the U.S. Such an analysis is particularly salient in light of patent issues. The Drug Price Competition and Patent Restoration Act of 1984 offers only limited protection to drug manufacturers,<sup>207</sup> and a company will be disinclined to invest large sums of money in clinical testing if its product is likely to be copied as

<sup>205</sup> *Cervical Cap Approved*, BBS NEWS (Dep't of Health and Human Servs., Wash., D.C.), May 23, 1988.

<sup>206</sup> Steve Lohr, *FDA Move Aids Tiny Company*, N.Y. TIMES, May 30, 1988, at

33.

<sup>207</sup> Peter B. Butt, *Landmark Pharmaceutical Law Enacted*, 1 HEALTH SCAN 11 (1984).

soon as the patent expires by other firms who did not have to incur the same initial expense. Moreover, manufacturers must consider whether or not to proceed with products likely to yield only a small return. In other words, the expense of testing (as well as the potential cost of litigation) must be considered within the framework of the modest profit margin offered by contraceptives like Norplant, the TUD and postcoital contraceptives, all of which do not require repeat purchases 208

Critics have attacked manufacturers of the long—lasting contraceptives Norplant and Depo Provera when they attempted to defray their costs by charging higher prices.<sup>209</sup> The cost of Norplant in the U.S. is approximately \$350, with some private physicians charging an additional \$500 or more for insertion. Moreover, Wyeth—Ayerst has not offered discounts to public agencies or charities as other contraceptive manufacturers often do. Consequently, critics charge that the company has limited use of the product to the very wealthy and the very poor who are insured by Medicaid.<sup>210</sup>

Supporters of Wyeth-Ayerst assert that the firm may not be solely to blame for its high prices. The price of Norplant may be an unintended result of legislation which requires drug companies to offer rebates to Medicaid equaling

<sup>208</sup>Mastroianni, Jr. et al., *supra* note 4, at 484.

<sup>209</sup>Warren E. Leary, *Long—Term Contraceptives' Cost Called Excessive*, N.Y. TIMES, Mar. 19, 1994, at 10.

<sup>210</sup>*Medicaid Widening the Use of Implant for Birth Control*, N.Y. TIMES, Dec. 17, 1992, at A1. According to representatives from the AGI, public programs will not invest in Norplant because clinics could use the same \$365 to buy four IUDs, or oral contraceptives for a year for 25 women.  
*Id.*

the difference between the average price and lowest price of the product. Such a law provides an incentive to the drug companies to keep their prices high.<sup>211</sup> In addition, Wyeth—Ayerst claims that the price of Norplant in the U.S. reflects the cost of training physicians how to insert and remove the product. Although the product is less expensive in other countries — in Finland it sells for about \$25 — the pharmaceutical company has not offered physician training in those nations.<sup>212</sup> Moreover, Wyeth-Ayerst has responded to criticisms by donating \$2.8 million to the Norplant Foundation, an organization formed to provide free Norplant kits to women not covered by Medicaid or private insurance.<sup>213</sup> Local governments have also tried to increase access to the product by creating experimental programs to purchase Norplant and Depo Provera for distribution to a broader

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#### D. FUNDING

While contraception had been the subject of study for centuries, the distribution of the Pill in 1960 enhanced popular interest in the field, which in turn inspired public grants for contraceptive research. The NICHD began making such grants in 1969. Two years later, the United States

<sup>211</sup>Sonia L. Nazario, *Breakthrough in Birth Control May Elude Poor*, WALL ST. J., Mar. 4, 1991, at B1.

<sup>213</sup>Medicaid Widening, *supra* note 210.

<sup>214</sup>*Wyeth-Ayerst's Norplant Being Purchased for Government Distribution to Non-Medicaid Poor*, Food Drug Cosm. L. Rep. (CCH), Pink Sheet, Jan. 18, 1993, at 10. Such programs have been established in Maryland and Virginia, and are being considered elsewhere. *Id.*

Agency for International Development (USAID) began channeling research and development money through the Population Council in New York and Family Health International in Research Triangle Park, North Carolina. However, the interest in contraceptive research waned over the next decade. By 1988, funding had dropped dramatically, and amounted to only about ten cents for each adult and child in the U.S.<sup>215</sup>

Recent reports indicate that the National Institute of Health (NIH) spends \$10 million annually on contraceptive research. USAID spends approximately \$15 million, but mostly on simple inexpensive methods that would be practical in developing nations.<sup>216</sup> Aside from NIH and USAID, there are few other sources of funding. WHO recently cut the budget of its human reproduction program, and out of all of the large American foundations, only the Rockefeller and Mellon Foundations are providing direct support for contraceptive development.<sup>217</sup> According to Steven Sinding of the Rockefeller Foundation, his organization is continuing to support contraceptive development because, [o]thers are pulling out. We've articulated as our object to breathe new life into the field.<sup>218</sup>

This lack of funding for research creates a self—perpetuating problem. When the number of grants decrease,

<sup>215</sup>Thomas, *supra* note 82, at 49—50.

<sup>216</sup>Herman, *supra* note 2, at 14. These figures are particularly notable in comparison to government allocations in other areas: \$35 billion in military research; \$1.7 billion in AIDS and AIDS—related research; \$120 million in breast cancer research. 138 CONG. REC. B 2927 (daily ed. May 5, 1992).

<sup>217</sup>Berman, *supra* note 2, at 14.

<sup>218</sup>*Id* at 15.

fewer scientists seek doctorate degrees in reproductive biology because they are unwilling to pursue an area of study where funding seems insecure.<sup>219</sup> With reproductive biology failing to attract skilled researchers, fewer developments are made. Consequently, the field becomes less appealing to investors and foundations, and the cycle continues.

## **VI. Solutions to the Problems Limiting New Development**

As in any crisis, it is easier to describe the problems leading to the slow pace of development in contraception, than to provide solutions. Nevertheless, although solutions to the problems hindering innovations in birth control, i.e. excessive product liability suits, negative political pressures, strict testing requirements, and insufficient research and funding, may be hard to come by, certain measures may be taken to ameliorate the present situation.

### **A. Product Liability**

One of the traditional suggestions for limiting product liability suits involves placing caps on punitive damages. The theory behind this recommendation holds that possible damage awards are so high that prospective plaintiffs, and particularly their attorneys, view bringing suit as akin to a lottery – with such a large potential payoff, almost any product liability litigation is worth a shot. Therefore,

<sup>219</sup>Thomas, *supra* note 82, at 68.

supporters of caps maintain that reducing the potential rewards of suit will decrease litigiousness.<sup>220</sup>

Opponents of caps voice concern that the threat of enormous liability costs are a necessary incentive to industry. They worry that if pharmaceutical companies could pre—determine their liability costs, they might distort their risk analysis to permit the distribution of unsafe products as long as the cost of litigation is low enough to allow them to maintain a profit margin. Moreover, opponents of damage caps assert that victims deserve compensation for their injuries, and juries may be the best mechanism for determining the appropriate amount of redress.<sup>221</sup>

In any case, legislation establishing caps on damages appears unlikely to be adopted by Congress any time soon. Over the past decade, tort reformers' Fairness in Product Liability bill, has been proposed several times in Congress; the bill has reached the Senate floor at least five times with no success. Most recently, the bill was defeated this past summer, after a filibuster.<sup>222</sup> The failure of the latest version of this tort reform bill is especially notable, because its sponsors mentioned several times during the debate that the measure did not include any caps on damages.<sup>223</sup> The absence of such provisions was intended as a

220138 CoNG. REc. S4682 (daily ed. Apr. 2, 1992).

<sup>221</sup>Andy Pasztor & Stephen Wermiel, *Plans for Product-Liability Bill Generate Consensus Among Senate Panel Members*, WALL ST. J., May 21, 1986, at 12.

<sup>222</sup>*Product Liability Legislation Defeated As Senate Fails to Curtail Filibuster*, 1994 Daily Rep. For Executives (BNA), June 29, 1994, at 123.

<sup>223</sup>CoNG. REc., *supra* note 220.

selling point – limitations on punitive damages were so controversial that they were eliminated as a concession to consumer groups and moderate members of Congress.<sup>224</sup>

Despite these past defeats, proponents of tort reform, and damage caps in particular, have lately expressed some optimism. The newly-elected Republican Congress has included tort reform as part of its Contract with America. One of the two tort reform bills presently being considered, new House Judiciary Chairman Henry Hyde's (R-IL) Common Sense Legal Reforms Act includes a provision capping punitive damages at \$250,000 or three times the award for economic damages, whichever is greater.<sup>225</sup> Nevertheless, some experts assert that the measure is unlikely to succeed, in part because tort reform is considered to be a partisan issue, and the Democrats have retained enough seats in the Senate to sustain a filibuster.<sup>226</sup>

In addition to supporting caps on damages, some commentators have proposed that a solution to the problem of excessive product liability suits lies in the statutory establishment of a regulatory compliance defense. With such a measure in place, pharmaceutical companies whose products obtain FDA approval would have some immunity from suit. In its February 1990 report, the National Research Council's Committee on Contraceptive Development (NRC-CCD) voiced its

<sup>224</sup> *Shift in Political Winds to Hit Product Safety and Liability*, 1995

Daily Rep. For Executives (BNA), Jan. 19, 1995 at 12.

<sup>225</sup> *Id*

<sup>226</sup> *Id*



support for congressional legislation establishing a regulatory compliance defense as well as uniform standards for product liability suits involving contraceptives.<sup>227</sup> Such a proposal was also incorporated in the tort reform measure defeated this past summer.<sup>228</sup>

The NRCCCD's proposed defense also included some notable exceptions. For instance, the NRCCCD asserted that the regulatory compliance defense would not be available if it were found that the manufacturer withheld relevant information from the FDA in the approval process, or if information developed by the company after approval had not been reviewed by the FDA for purposes of determining whether the contraceptive, its marketing, or its labeling should be changed.<sup>229</sup> Relying on these exceptions, it seems as if the NRCCCD's proposal would permit cases like Wells v. Ortho Pharmaceutical Corp. to go forward, because the plaintiff could argue that the FDA did not know when it approved spermicides for post-conception use that a member of its advisory committee had previously consulted with Ortho Pharmaceutical Corp.<sup>230</sup> The NRCCCD's proposal attempts to strike a balance between protecting companies from suit and providing the proper incentives for companies to protect consumers from harm. However, because some determination would be necessary to assess whether a manufacturer properly

<sup>227</sup>Mastroianni, Jr. et. al., *supra* note 4, at 484.

<sup>228</sup>*Product Liability Legis. Defeated*, *supra* note 222.

<sup>229</sup>Mastroianni, Jr. et. al., *supra* note 4, at 484.

<sup>230</sup>Wells v. Ortho Pharmaceutical Corp., 615 F. Supp. 262 (N.D. Ga. 1985), *aff'd.*, 788 F.2d 741 (11th Cir. 1986).

informed the FDA, this measure might not actually reduce the amount of litigation. Moreover, it is unclear whether the exceptions built into the NRCCCD's proposal would serve to eviscerate the measure or would provide positive incentives to the manufacturer and prevent industry manipulation of the

FDA.

Another means of dealing with the product liability issue is suggested by the National Childhood Vaccine Injury Act of 1986.<sup>231</sup> The Act provides for a federal no—fault compensation system which provides quick and certain remedies for individuals injured by vaccines. Anyone injured by a vaccine must go through the compensation program, and judgments and awards entered under the program must be expressly rejected before other remedies can be pursued. If an individual rejects the award granted through the no-fault program, she may take action directly against the vaccine manufacturer by filing a civil suit. However, stricter substantive and procedural requirements are established for recovery of damages in civil court. Funding for the program is provided through a tax on designated childhood vaccines.<sup>232</sup>

This no—fault program was designed to encourage manufacturers to enter the vaccine market, thereby creating a larger pool of vaccines for preventing disease and otherwise

<sup>231</sup>B.R. RZP. No. 908, 99th Cong., 2d Sess., pt. 1, at 1 (1986).

<sup>232</sup> *Id.* at 3. In addition to establishing a new recovery system, the vaccine program places additional burdens on manufacturers. They must keep records on the production, testing, and handling of their products, and report any potential problems to an appropriate federal agency within 24 hours. The Secretary of BBS has the authority to recall hazardous products, and to perform studies on the products and the sufficiency of their labels. *Id.* at 4.

at 6.

<sup>234</sup> *Id*

improving public health. The circumstances leading to the passage of the bill mirror those now surrounding the development of contraceptives. Vaccine manufacturers were facing high tort liability costs from suits filed by individuals injured by their products. The pharmaceutical companies had responded by raising their prices or by abandoning the vaccine market. Despite the occasional grave injury, most experts (including public health officials, physicians and parent groups), believed that it was worthwhile to continue to prescribe the products because of the larger benefit for society as a whole.<sup>233</sup>

The no—fault scheme for vaccine liability benefits both consumers and manufacturers. Although consumers who accept the award through the no-fault system give up the opportunity for a multi-million dollar settlement, for many, it is a welcome trade. Under the no—fault system, the recovery process has been streamlined, reducing transaction costs and increasing certainty of recovery. Manufacturers profit from the system as well, because much of the expense of litigation, including investments of both time and money, has been eliminated. In addition, by funding the compensation through a tax, rather than manufacturers, the program allows companies to reduce the costs of their liability insurance and remain in business.<sup>234</sup> Enabling the companies to remain solvent, the no-fault program ultimately protects all

<sup>235</sup> *Id* at 7.

<sup>236</sup> *See* note 128, *supra*.

consumers by eliminating the health hazards that would occur if vaccines were not available.<sup>235</sup>

Such a no—fault system may be one solution to the product liability problem facing contraceptive developers. Not only are the market conditions similar, but the consequences of the absence of birth control choices, including unplanned pregnancy and its attendant social ills, are arguably no less hazardous to society than a shortage of vaccines. Nevertheless, the applicability of such a program to contraceptive development remains questionable because birth control is more politically divisive than vaccination.

Finally, another means of minimizing the impact of product liability suits may be through the establishment of single drug companies. Such firms could either be for-profit entities subsidized by government tax breaks, structurally similar to those companies presently producing orphan drugs, or non—profit organizations. Etienne—Emile Baulieu, the developer of RU-4 86, has suggested that creation of such single—drug companies would facilitate the distribution of controversial drugs like RU—486 because the companies would be insulated from the threat of boycott.<sup>236</sup> A potential problem with such a structure would be the difficulty of attracting investors to a business that could grow only in a linear manner. After all, any product diversification would

diminish the organization's protection from suit or negative market forces.

B. Politics

Instead of allowing the political debate about contraceptives to focus on the morally and politically divisive issue of abortion, pharmaceutical companies should characterize contraception as a women's health issue. Thus, the companies must emphasize the link between birth control and the prevention of AIDS and other STDs. In addition, they must capitalize on the momentum of the recent movement to address women's health concerns, most notably in the area of breast cancer.

One means of overcoming some of the pharmaceutical companies' reticence in developing new contraception is to remind manufacturers of the pressing need to develop products that help prevent the transmission of the virus that causes AIDS. When contraception is viewed as a life-saving necessity, rather than simply as a means of preventing pregnancy, it may gain more political acceptance and broader—based public support. The link between contraception and disease prevention is becoming more well-known and has fueled interest in developing more contraceptives like the male condom, which simultaneously prevent conception and disease. Indeed, at least one commentator has suggested that a physician who prescribes a non-barrier method and fails to

warn about possible infection may be guilty of malpractice for the omission.<sup>237</sup>

Because references to AIDS also provoke some negative political and moral reactions, particularly by those who link the spread of the disease to promiscuity, pharmaceutical companies may be more inclined to characterize contraception as a women's health issue and align themselves with the growing movement to combat breast cancer. Public awareness of breast cancer has increased dramatically over the past few years.<sup>238</sup> Moreover, the issue has garnered increased funding and political support. Indeed, for the past few years, Congress has ordained October as Breast Cancer Awareness month.<sup>239</sup> A movement to increase contraceptive options has the potential of arousing similar positive publicity. Just as the risk of breast cancer cuts across all socio-economic lines, all women need new birth control alternatives.

Yet ironically, the fact that all segments of society would benefit from contraceptive development may also diminish the likelihood of inspiring a political movement to enhance birth control options. When benefits from political action are diffuse, a free-rider problem appears and people are less motivated to take action. Moreover, women's organizations, who would seem to be the most likely voice for political change, are not united in their views on contraception.

<sup>237</sup>Thomas, *supra* note 82, at 67.

<sup>238</sup>140 CoNG. REC. B 10428 (daily ed. Sept. 30, 1994).

<sup>239</sup>*Id*

### C. Testing

The NRCCCD has recommended simplifying FDA regulations for the toxicological and clinical testing of contraceptives, so that the FDA'S standards will conform with the guidelines of WHO and other industrialized nations. To this end, the NRCCCD suggested an international conference on the regulation of contraceptive development.<sup>240</sup> Such a conference would be an important first step towards regulatory reform. Moreover, by meeting with health organizations worldwide, American fertility scientists may be able to obtain international sponsorship for their research.

The NRCCCD also noted that the FDA's current stringent policies reflect the agency's presumption that contraceptives must meet a higher standard because they are used primarily by healthy people. According to the NRCCCD, the FDA's position neglects the fact that currently available methods do not meet the needs of many people and that the risks of pregnancy, labor and delivery for these individuals are often greater than the risks associated with the methods of birth control.<sup>241</sup> Consequently, the committee recommended that FDA revise its procedures to recognize the special safety advantages of new methods for identifiable groups not adequately served by already approved contraceptive methods.<sup>242</sup> Moreover, the committee suggested that the FDA approve a drug even if that drug or device presents a risk to

<sup>240</sup>Mastroianni, Jr. et al., *supra* note 4, at 483.

<sup>241</sup>*Id.* at 484.

<sup>242</sup>*Id.*

some populations, if it can be shown that the new contraceptive also offers a safety advantage for other users when compared with that group's actual contraceptive practice, including the failure to use any method at all. Labeling for these new products could include a listing of possible adverse effects, and use of the product could be restricted by physicians to a well—defined population. Finally, approval of these riskier products could be accompanied by strict post-marketing surveillance by the FDA, and long-term epidemiological studies.<sup>243</sup>

Just as the political problems facing contraceptive development may be reduced by aligning birth control with controlling STDs and AIDS, some testing obstacles may also be overcome if contraception is seen as necessary tool of disease prevention. Already, streamlined testing procedures have been implemented in response to the AIDS crisis. Concern that women needed a way to protect themselves from infection prompted the FDA in August 1989 to propose guidelines for an abbreviated review process for female barrier contraceptives that prevent STDs. This approach has allowed for the marketing of these products after the second phase of clinical trials. The products must be advertised as effective against STDs, and include a disclaimer noting that their efficacy against contraception has not yet been proved. Meanwhile post—marketing studies on their efficacy as



contraception must continue.<sup>244</sup> Using this accelerated approval process, the FDA's Obstetrics and Gynecology Panel recommended conditional approval of the female condom in December 1992, based on efficacy data derived from a pregnancy study.<sup>245</sup>

The FDA's proposal for interim marketing was praised by members of the pharmaceutical industry and even gained the tentative support of the National Women's Health Network.<sup>246</sup> The AGI also offered its support of the FDA's proposal for quick approval, as long as the Phase II trials included both a large enough sample and extensive post-marketing studies. Indeed, Jeannie Rosoff, president of AGI, suggested that the FDA expand upon its idea of an abbreviated process, stating, [i]f a streamlined process is both possible and desirable for a particular purpose (STD prevention) as it evidently is, why is it not also possible and desirable for the development of female contraceptive methods for the prevention of unintended pregnancy?<sup>247</sup> Among its other suggestions, AGI recommended including some less healthy participants in the study, e.g., individuals suffering from hypertension, to

<sup>244</sup> *Barrier Contraceptives Should Bypass Phase III Clinical Study*, MDDI REP., Sept. 4, 1989, at 12. Phase I studies would track 10 to 20 females; Phase II would involve at least 200 subjects; and the post-market Phase III would compare the use of the device over a 12 month period by a minimum of 1100 women to the same number of women using a currently marketed product. *Id.* at 13.

<sup>245</sup> Mireya Navarro, *Female Condom is Winning Favor*, N. Y. TIMES, Dec. 15, 1993, at B1.

<sup>246</sup> *Id.*

<sup>247</sup> Letter from Jeannie Rosoff, Pres., AGI, to Dockets Mgmt. Branch, FDA (July 31, 1990) (on file with the Regulatory Watchdog Serv.).

determine the applicability of contraceptive methods to such sub—populations  
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Several other suggestions have been offered for reducing the extensive delays in the FDA approval process. One commentator recommended that the U.S. contract out the performance of product reviews to private organizations.<sup>249</sup> While such a program may increase efficiency, it is not clear how to prevent an outside contractor, particularly one subject to tort liability, from proceeding slowly in order to avoid approval of a thalidomide. A private review program would necessitate strict safeguards to prevent manipulation by industry to the detriment of consumers. Generally, the FDA would still have to play a significant oversight role to ensure that private contractors find the proper balance between efficiency and thoroughness.

Even if the FDA were reluctant to cede responsibility for approval to the private sector, the agency might at least adopt a policy to recognize clinical studies performed in foreign countries. Such a measure would limit duplicate testing on animals and humans, thereby expediting the review process, and reducing the need for additional trial participants.<sup>250</sup> Of course, before adopting a policy which permitted reliance on foreign studies, the FDA would need to establish guidelines for assessing their quality.

<sup>248</sup> *Id.* AGI also asked for increased information on the outcome of the cases where contraceptive failure occurred, i.e., whether there was a birth or an abortion, and for complete pre—trial counseling for the subjects. *Id.*

<sup>249</sup> Chicoine, *supra* note 118, at 90 n.68.

<sup>250</sup> *Id.* at 90 n.69.

In addition, the FDA might follow the example set by Great Britain's CSM and shift agency focus from premarket screening to post-market testing. In order to facilitate this process, the FDA could establish a user registry system for newly—approved products.<sup>251</sup> Patients could use a toll-free number to alert the agency of complaints, and the agency would be able to track the population of users to determine the need for product warnings or recalls.<sup>252</sup> Similarly, the FDA could adopt a pro—active approach toward regulation and propose guidelines for the proper use of contraceptives as it did in the 1970s when it evaluated DES for post—coital use.<sup>253</sup> Because such a policy seems to be extremely resource— intensive, the agency would be wise to limit its efforts to circumstances where manufacturers have little incentive to pursue approval, such as assessments of unapproved uses of already—approved products.

Another possible means of encouraging research would involve an examination of the role that patent regulation has had on contraceptive development. Such an inquiry may reveal that pharmaceutical firms would do more contraceptive research if they could protect the fruits of their labors for a longer period of time. On the other hand, changing patent law to extend the protection period may act to the detriment of consumers by further limiting choice and/or inflating

<sup>251</sup>Galen, *supra* note 69.

<sup>252</sup> *Oral Contraceptive Patient Label: One Page Summary Recommended*, Food

Drug and Cosm. L. Rep. (CCH), Pink Sheet, Nov. 1, 1993, at 1.

<sup>253</sup>Hutt, *supra* note 190, at 1653.

prices. Moreover, such a change may not be needed if tort reform proposals, making the expense of research more justifiable to industry, were enacted.

D. Funding

To increase competition in the field of long—acting contraceptives, Representative Wyden (D—OR) of the House Small Business/Regulation Subcommittee, proposed that, the government fund an accelerated R & D effort to create more products.<sup>254</sup> Representatives from the pharmaceutical trade group, National Family Planning and Reproductive Health Association agreed with Wyden and also proposed different ways to build a mutually beneficial economic relationship between manufacturers and government. For example, the trade group suggested that the government offer grants to small pharmaceuticals manufacturers to develop contraceptives under contracts stipulating that the manufacturers must sell the product to the government at a lower public price when it comes to market. The government would then distribute the products to federal and non—profit clinics. Other suggestions for saving government money included: requiring manufacturers to offer a lower public price for the results of research funded with public money, and bulk purchasing of new products by the government.<sup>255</sup>

<sup>254</sup> *Upjohn Discussing Depo Provera Discount for Family Planning Group; Surgeon General Elders Tries Gentle Persuasion on Long—Acting*

*Contraceptive Prices*, Food Drug and Cosm. L. Rep. (CCB), Pink Sheet, Mar. 21, 1994, at 4.

<sup>255</sup> *Id*

Congress has also suggested other means of enhancing funding for contraceptive research. Congress first proposed The Contraceptive and Infertility Research Centers Act on April 25, 1991, as part of an omnibus package of legislation referred to as the Women's Health Equity Act. The purpose of the bill was to conduct clinical and applied research; train physicians, scientists and other allied health professionals; develop model continuing education programs for such professionals; and disseminate information to them.<sup>256</sup> The bill also attempted to attract more researchers to this field by establishing a loan repayment program for scientists involved in contraceptive or infertility research. In addition, the bill would facilitate research by authorizing payment for the subjects of such studies. The act allocated \$15 million a year for 1992—1994; \$20 million for 1995, and whatever would be necessary for 1996.<sup>257</sup> Despite the fact that its sponsors were on both sides of the abortion debate, and attempted to defuse any controversy surrounding the measure,<sup>258</sup> the bill failed to pass in 1991. However, \$3 million was provided for the development of these centers through the NIH budget. The measure failed to pass again when it was re—introduced in 1993.<sup>259</sup>

256139 CONG. RZC. S527 (daily ed. Jan. 21, 1993).

<sup>258</sup> *Id.* As Senate sponsor Sen. Barkin (D-IL) stated, [w]hatever positions we take on the question of abortion, if we are committed to helping couples have children who want them, and to reducing the incidence of abortion in the case of those who do not, this bill is a step in the right direction. *Id.*

<sup>259</sup> *Id.*

The failure of the government to promote effectively contraceptive research, highlights the need for action from the private sector. More specifically, large private foundations, like the Ford and Carnegie Foundations, which are often willing to support programs that deal with the societal results of unplanned pregnancy, must step in to address the causes of these social ills. In addition, organizations like Planned Parenthood should take a more active role in funding new contraceptive alternatives.

The NRCCCD has also recommended more funding by the government and by non-profit foundations, noting that the government and other investors have to ensure long-term stability for research projects. The NRCCCD blamed the absence of progress in this area on the fluctuation in funding over the past decades, noting that this situation frightens off serious clinical investigators concerned with job security.<sup>260</sup> Clearly, increasing funding will attract more scientists to this field. Thus, by pledging financial support, the government and foundations can end the negative cycle stymieing contraceptive development.

## **VII. CONCLUSION**

The number of unplanned pregnancies in this country and the limited contraceptive options demonstrate a clear need for new birth control alternatives in the United States. Nevertheless, pharmaceutical companies generally believe that

<sup>260</sup>Mastroianni Jr. et al., *supra* note 4, at 483.

investing in contraception research and testing makes little financial sense. As Roderick L. Mackenzie notes, industry finds focusing on drugs intended for other uses, like ulcers, immuno—therapy and cardiovascular disease more worthwhile. Mackenzie has observed that, [un those fields you don't have to be 100 percent effective, you can be 70 percent effective. Your side effects don't have to be zero, they can be 20 percent and still not be unacceptable. You don't have a sea of bad publicity endangering your other drugs, and your researchers can get Nobel Prizes.<sup>261</sup>

The problems hindering contraceptive development are large, but hardly seem insurmountable. In order to encourage development in this field, pharmaceutical companies, government and non—profit public health and women's rights organizations must make a commitment to address these obstacles and foster a positive climate for change.

<sup>261</sup>Hilts, *supra* note 13, at 70.